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IMPACT OF PHARMACOVIGILANCE AWARENESS AMONG UNDERGRADUATE STUDENTS IN A TERTIARY CARE HOSPITAL & MEDICAL COLLEGE OF NORTH INDIA

Pharmacology

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KEYWORDS

Introduction

India is home to one of the largest drug consuming populations in the world. There are between 60,000–80,000 brands of drugs available in the Indian market that are irrationally prescribed and misused [1]. This may be due to lack of medication safety practices, and failures in the regulatory environment. The misuse and faulty prescribing accounts for development of many adverse drug reactions (ADRs) that are one of the major causes of mortality and morbidity, unplanned hospitalization, and increased healthcare cost, worldwide [2-5]. Thus, early identification of ADRs is extremely important for both government and non-government health care organizations.

A large number of drugs are introduced in the Indian market every year, but the data pertaining to the Indian population is sparse. Therefore, our population is at greater risk due to delayed reporting and a culture of non- reporting by health service providers. Our country is at a nascent stage of implementation of pharmacovigilance program, forming only 2% of total ADR being reported worldwide.

The World Health Organization (WHO) defines ADRs as any noxious, unintended, and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or treatment of the disease [6]. The worldwide incidence of ADR occurrence leading to emergency hospitalization ranges from 0.2 to 41.3%, out of which 28.9% of ADRs are preventable [7]. In 2012, a meta-analysis showed that 52% of ADR-related emergency hospitalizations and 45% of ADRs in inpatients were preventable [8]. Moreover, post-marketing safety studies have been shown to be very important in identifying possible risk factors associated with the use of new drugs in the general population and the contribution of health professionals is significant in reporting suspected ADRs to strengthen the signal detection.

Pharmacovigilance (PV) is defined as a sum of activities related to the detection, assessment, understanding, and prevention of ADRs caused by drugs [9]. Spontaneous reporting of suspected ADRs to PV centers is of utmost importance to generate the safety data of marketed drugs. Indeed, understanding the importance of reporting ADRs, national and international organizations urged health professionals to prioritize ADR reporting in order to curtail ADR- related problems. In India, the national Pharmacovigilance Programme of India (PvPI) was established by the Central Drugs Standard Control Organization (CDSCO) in 2004 to monitor ADRs and to provide drug safety reports to the WHO-ADR monitoring center in Uppsala, Sweden [9]. To coordinate ADR monitoring throughout India, the Drug Controller General of India (DCGI) and Indian Council of Medical Research (ICMR) have established many peripheral PV centers in various hospitals located in major Indian cities [10, 11].

Furthermore, it is evident that under-reporting of suspected ADRs by health professionals is a widespread problem in India [12]. For instance, the contribution of ADR reporting from India was below 1%, which highlights the existing gaps in success of the PV programme [13]. There are several local and national projects that are aimed at improving and promoting PV activities in India [14-18]. These initiatives seek to increase awareness of the PV programme among health professionals and to improve ADR reporting. In particular, a better understanding of these issues could help national organizations in developing strategies for improvement of PV activities. Hitherto, no systematic review on this topic was identified from India. In order to gather data from the existing evidence pertaining to knowledge, attitude and practice (KAP) of ADR reporting and PV in the health professionals, a systematic review of current literature and a meta-analysis needs to be done.

The legal obligation to report ADRs requires health professionals to have the knowledge and skills to recognize and adequately report these reactions. During their medical training, medical students are typically taught how to prescribe rationally on the basis of the WHO Guide to Good Prescribing [13–15], and the last step of the six-step method covers the follow-up of prescribing; however, it is not known whether medical students are adequately prepared for their role in monitoring and reporting ADRs. Previous studies have shown that pharmacy students have an insufficient knowledge of pharmacovigilance and ADR reporting [1, 16]. We expected a similar insufficient preparedness among medical students, and by identifying the nature of this insufficiency, we would be able to improve future (medical) pharmacovigilance education. Therefore, the primary objective of this study was to investigate whether medical students are sufficiently prepared for their role in pharmacovigilance. A secondary objective was to evaluate the intention/attitudes and skills/knowledge of these students towards pharmacovigilance and ADR reporting.

Methods

Study set up

The present study was conducted among the second year MBBS undergraduate students in the Department of Pharmacology, North DMC Medical College (NDMC MC) and Hindu Rao Hospital, New Delhi, India.

Study design

A cross-sectional, voluntary, self-administered questionnaire survey was administered that consisted of 21 questions assessing subjects' knowledge and attitude and practice regarding pharmacovigilance and ADR monitoring. A pre-test and post-test experimental design was used. All the questions with similar ideas were grouped together either as knowledge items or attitude items (Table1). Questionnaire was filled anonymously by the medical undergraduates.

The questionnaire was pilot tested in a small group of 10 subjects to assess its reproducibility and suitability. Feedback was taken from these participants regarding their understanding with respect to the questionnaire. The Cronbach alpha was estimated to be 0.7, suggesting

good internal consistency and an overall reliability. After completion of the pre-test, all the participants were educated in a one hour interactive educational lecture about pharmacovigilance, causality assessment, ADR monitoring and its importance in health care set up. The post test was undertaken after 2 weeks of the educational lecture. The same group of students were used in the pre-test and post-test.

Ethical approval

The study was conducted after approval by the Institutional Ethics Committee of North DMC Medical College (NDMC MC) and Hindu Rao Hospital, New Delhi, India.

Statistical analysis

Responses to questions were calculated as descriptive data (absolute numbers and percentages). Changes in pre-test and post-test scores were analyzed.

Results

A total of 120 undergraduates were administered the questionnaire in the study. Among them, 100 (96%) students participated voluntarily and completed both the pre-test and post-test. A validated set of 21 questions were administered to students both pre and post test. **Table 1** describes dimension-wise overview of the items on knowledge and attitude included in the questionnaire. **Table 2** shows responses to knowledge and attitude questionnaire of undergraduate medical professionals on a pre-test and post-test expressed as absolute numbers (%). **Table 3** deals with questions related to practice.

Knowledge Analysis

Lack of knowledge regarding pharmacovigilance was evident from the fact that only one third of students (36%) were aware and could correctly define Pharmacovigilance in pretest whereas post test there was a significant improvement and 98% gave the correct response. Although during pretest more than half of students (60%) were aware regarding purpose of Pharmacovigilance, but post lecture the concept became clearer and 84% students gave the correct answer. After identification of an ADR, a form needs to be filled and causality assessment of the ADR is done. Causality assessment is a major step in the process of reporting, however more than half of the participants were unaware of the scale used in ADR reporting. Moreover once the assessment is done the ADR has to be reported within 15 days to the central data base. Knowledge regarding this was also very sparse since only less than a quartile (23%) knew in how many days an ADR needs to be reported whereas this improved significantly post test (62%). Moreover students were also unaware of the Vigiflow (central data base) as only one third of participants (33%) gave correct response during pretest. However after the lecture the results improved to 57%.

The participants were also unaware of the post marketing surveillance conducted by the companies for Pharmacovigilance as only 40% respondents gave the correct response whereas post assessment 73% gave correct answer. International center for ADR monitoring was known to only 18% students and the regulatory body for drug safety issues was known to only 54% of the respondents. Only 46% of students knew about the regulatory body in India for ADR monitoring in pretest however post test the 68% students gave the correct response. The knowledge regarding who can report an ADR was surprisingly low i.e 23% during pretest as compared to 87% in the post test. Students had the least knowledge about which ADR should be reported to the Pharmacovigilance software.

Attitude

Lack of time was listed one of the major reasons for unwillingness to report an ADR in both pretest (34%) and post test (38%) . This attitude showcases the passive perception of some of the health care professionals ignoring the importance of reporting ADRs. Almost one third of participants (37%) reported difficulty in deciding if the ADR has occurred or not, however post test there was decrease in trend (32%). Almost 90% of students thought it to be a professional obligation to report ADR post test as compared to pre test (38%). Among the participants only 48% believed that ADR monitoring is necessary, however this concept improved as post test more than 90% students believed that it is necesssary to report an ADR. Also only 42% thought that there should be an ADR monitoring center in every hospital, which improved to 62 % post lecture. Although a large no of participants 90% were of the opinion that pharmacovigilance should be taught in detail to health care professionals this improved further to 98% post test.

Practice

Only 16% participants had read an article regarding ADRs however post test 83% participants, read an article regarding ADRs , moreover only 23% reported to have come across an ADR during pretest whereas post test 44% students had come across an ADR.

In addition, gives hope that educational interventions and training programmes during medical curriculum could enhance the knowledge of the health care professionals

Discussion

ADR reporting forms an essential component of pharmacovigilance program. The attitude towards ADR reporting is very nonchalant in our country , as observed in a study by hardeep et al one of the major reasons of non reporting is the lack of knowledge about reporting procedure.(Hardeep et al). Moreover medical professions are unaware of the process of reporting whom to report how to report and when to report [19]. WHO defines Pharmacovigilance as "The science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem" [20]. Currently, ADR reporting system is not completely flourished, as our country is in the process of implementing PvPI in a phase wise manner across the nation. Hence pharmacovigilance related exercises should be introduced during undergraduate and post graduate tenure to bring ADR reporting into practice. This will further enhance their knowledge and develop positive attitude towards ADR reporting. Hence our study aimed to identify the lacunae in the Knowledge, attitude and practice among medical undergraduates and the impact of educational intervention in form of a lecture among them.

Approximately one third of the participants were not aware of definition of Pharmacovigilance. This suggests a lack of knowledge in our study participants regarding the concept and purpose of Pharmacovigilance and the importance of ADR reporting. Also it was observed that after the educative lecture post test there was major improvement in the knowledge of Pharmacovigilance. Thus it is necessary to educate our undergraduates in order to promote awareness about ADR reporting. For instance, many participants were not aware that ADR can only be reported within 90 days of their occurrence and only about a quarter of them know that ADRs from our hospital are not directly sent to WHO Uppsala monitoring centre Sweden. This fact needs to be emphasized and awareness should be spread regarding the fact that all ADRs from our hospital are first forwarded to the national coordinating centre (Indian Pharmacopoeia Commission) located in Ghaziabad.

Knowledge about who can report ADR was uncertain in our study as only 54.4% of the participants felt that a patient can also directly report an ADR. These findings are in line with a similar study conducted in a tertiary care hospital [21]. Among participants 81.2% answered that health care professionals can report an ADR only after confirmation of causality due to a drug which is in line with a recent study where 82.5% incorrectly noted that an ADR related to a particular drug should be confirmed before it is to be reported [22]. In line with the finding of Desai CK et al, where 56% of the respondents said that they would like to report only serious ADRs, it was found that 67.1% of the students in our study consider that only serious ADR is to be reported but it is not as per the guideline of the PvPI [23]. It becomes necessary to report any untoward reaction of any medicinal product to assess its safety and efficacy and to ensure better patient outcome. Moreover, majority of them were aware of the fact that ADR monitoring includes reporting due to allopathic and alternative medicines, blood products and vaccines and many were aware regarding the functioning of pharmacovigilance centre.

Medicinal products are associated with therapeutic effects as well as adverse effects. Clinical trial conducted prior to the drug approval for its safety and efficacy cannot uncover every aspect of untoward effect of the approved drug. Some of these are only identified after the drug is widely used by a large community of the people during the post marketing trials. A large proportion of the students in the study believe that all ADRs are not known when a new drug is commercialized which is in contrast to a recent study conducted in India [24]. However, almost three quarter of the respondents believe that all ADRs are not due to known pharmacological actions of the therapeutic agent.

Knowledge is considered a prerequisite and attitude a determinant of ultimate ADR reporting [25]. Overall attitude of responders towards

ADR reporting was good. In line with the previous studies more than three quarter of the respondents in our study agreed that ADR reporting is their professional responsibility to achieve better patient care and safety [26] In spite of this positive attitude, 32.2% of the participants still believe that ADRs can be reported only after obtaining consent of the patient and treating physician while 67.1% admitted that financial incentives for ADR reporting could improve pharmacovigilance practice among health care professionals which is in line with similar studies conducted amongst health care professionals [27]. It is also a point of concern that 43.3% of the respondents were not aware whether ADR reporting causes legal challenges for the reporting physician which is at par of the finding of Ray D et al and Hanafi S et al [26].

Underreporting of ADRs is very prevalent in our country, in spite of constant dedication of PvPI towards instilling a culture of ADR monitoring. There is a constant requirement for training programmes at regular intervals and endorsement of strict regulations for ADR reporting among healthcare professionals. The ADR reporting rate in India is below 1% compared to the worldwide rate of 5% [28]. Various previous studies have found that underreporting of ADR is related with shortcomings in the knowledge and attitude among healthcare professionals [29]. Reporting of even a single ADR was felt significant in improving the national database by almost three quarter of the respondents which is in line with a previous study [30]. Evidence from various studies suggested that some of the factors discouraging ADR reporting were lack of time to report an ADR, lack of responsibility and no incentives for ADR reporting [31]. However, our study participants (70.8%) did not note time as a critical obstruction towards ADR reporting, which is in line with some recent studies by Passier et al and Gupta P et al.

Recently, a meta-analysis showed that 52% of ADR-related emergency hospitalizations and 45% of ADRs in inpatients were preventable [32]. Moreover, after marketing of a new drug in the population their safety studies shown to be very important in identifying possible risk factors associated with it. Signal detection can be strengthened by the active contribution of health care professionals. More than three quarter of the undergraduates were aware that adequate knowledge could prevent ADRs and ensure rapid signal detection with almost 90% of them ensures to be more vigilant in future towards ADR reporting, which are in line with the findings of a similar study [33]. Hence, it is essential for all of them to study the safety profiles of the marketed medications before prescribing them and to be vigilant in reporting any suspected ADRs to the pharmacovigilance centres.

Medical undergraduates could play a prime role in successful implementation of pharmacovigilance program if adequate knowledge and aptitude/ expertise are imparted to them during undergraduate training career, but at present they don't have any significant role to play which is due to inadequate training to them regarding ADR reporting [34]. It can be overcome by educational intervention program like collection of ADRs as a part of undergraduate practicals and carrying out workshops on pharmacovigilance and causality assessment. This will allow a transformation to an evidence-based strategian approach and strengthen the architecture of pharmacovigilance.

The results of the present study also may provide a fortunate opportunity for future implementation of teaching modules and curricular planning of topics such as pharmacovigilance and ADR reporting where misconceptions exist.

Conclusion

Findings suggest that medical undergraduates in our study are lacking in understanding of the facts about ADR reporting and may require more information on the national pharmacovigilance system and the process involved in ADR reporting. In addition, educational intervention impacts the knowledge and attitude scores of the new generation of health professionals and could minimize the frequency of risk factors and improves the safety of patient's health.

A pre and post-interventional comparative study to assess the knowledge, attitude and practices of pharmacovigilance among second year medical students of a government medical college of North India

Table 1.Response of students to knowledge based questions

Question No.	Pre Intervention correct Responses (%) N=100	Post Intervention correct Responses(%) N=100
Q1.Define Pharmacovigilance? a) The science of monitoring ADR's happening in a Hospital b) The process of improving the safety of Drugs c) The detection, assessment, understanding & prevention of adverse effects d) The science detecting the type & incidence of ADR after drug is marketed.	36	98
Q2. The important purpose of Pharmacovigilance is (Most appropriate one) a) To identify safety of drugs b) To calculate incidence of ADR's c) To identify predisposing factors to ADR's d) To identify unrecognized ADR's	60	84
Q3.Which of the following methods is commonly employed by the pharmaceutical companies to monitor adverse drug reactions of new drugs once they are launched in the market? a) Meta analysis b) Post Marketing Surveillance (PMS) studies. c) Population studies d) Regression analysis	40	73
Q4.A serious adverse Event in India should be reported to the Regulatory body within a) One day b) Seven calendar days c) Fourteen calendar days d) Fifteen Calendar days	25	62
Q5.The international center for adverse drug reaction monitoring is located in a) Unites States of America b) Australia c) France d) Sweden	18	61
Q6.One of the following is the agency in Unites States of America involved in drug safety issues. a) American Society of Health System Pharmacists (ASHP) b) United States food and drug administration (US FDA) c) American Medical Association (AMA) d) American Pharmaceutical Association (APA)	54	92

Q7.One of the following is a major risk factor for the occurrence of maximum adverse drug reactions a) Arthritis b) Renal failure c) Visual impairment d) Vacuities	60	88
Q8. In India which Regulatory body is responsible for monitoring of ADR's? a) Central Drugs Standard Control Organization b) Indian Institute of sciences c) Pharmacy Council of India d) Medical Council of India	46	68
Q9.Which of the following scales is most commonly used to establish the causality of an ADR? a) Hartwig scale b) Naranjo algorithm c) Schumock and Thornton scale d) Karch & Lasagna scale	27	57
Q10.Match the ADR reporting systems to the respective countries. (Write the number in the appropriate boxes) 1) Yellow card India 2) Green card Australia 3) ADR reporting Form United Kingdom 4) Blue card Scotland	19	53
Q11.One among these is a Regional Pharmacovigilance centre? a) Kasturba Hospital, Manipal b) JIPMER, Pondicherry c) JSS Medical College & Hospital, Mysore d) CMC, Vellore	41	73
Q12.Which one of the following is the 'WHO online database' for reporting ADRs? a) ADR advisory committtee b) Medsafe c) Vigibase d) Med watch	33	64
Q13. Rare ADRs can be identified in the following phase of a clinical trial a) During phase-1 clinical trials b) During phase-2 clinical trials c) During phase-3 clinical trials d) During phase-4 clinical trials	24	85
Q14. The healthcare professionals responsible for reporting ADR in a hospital is/are a) Doctor b) Pharmacist c) Nurses d) All of the above	23	87

Table 2.Response of students to attitude based questions

Question No.	PRE INTERVENTION RESPONSE	POST INTERVENTION RESPONSE
15. Which among the following factors discourage you from reporting Adverse Drug Reactions? (Any one only)		
a) Non-remuneration for reporting	8	5
b) Lack of time to report ADR	34	38
c) A single unreported case may not affect ADR database	21	25
d) Difficult to decide whether ADR has occurred or not	37	32
16. Do you think reporting is a professional obligation for you?		
a) Yes	38	89
b) No	26	
c) Don't know	29	
d) Perhaps	7	11
17. What is your opinion about establishing ADR monitoring centre in every hospital?		
a) Should be in every hospital	42	62
b) Not necessary in every hospital	13	3
c) One in a city is sufficient	18	7
d) Depends on number of bed size in the hospitals.	27	28
18) Do you think reporting of adverse drug reaction is necessary?		
a) Yes	97	100
b) No	3	
19) Do you think Pharmacovigilance should be taught in detail to healthcare professionals?	0	0
a) Yes	91	99
b) No	9	1

Table 3.Response of students to practice based questions

QUESTIONS	PRE INTERVENTION RESPONSE	POST INTERVENTION RESPONSE
Q19. Have you anytime read any article on prevention of adverse drug reactions?		
a) Yes	16	83
b) No	84	17
Q20. Have you ever come across with an ADR?		
a) Yes	26	44
b) No	74	56
Q21.Have you ever been trained on how to report Adverse Drug Reaction (ADR)?		
a) Yes	00	99
b) No	100	00

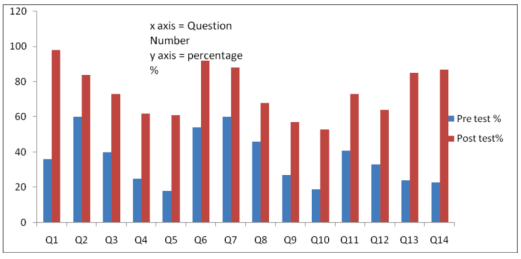

FIGURE 1: PRETEST AND POSTTEST COMPARISONS OF KNOWLEDGE OF PHARMACOVIGILANCE AMONG UNDER GRADUATE STUDENTS

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