Original Research Article

An educational intervention to assess knowledge and attitude of pharmacovigilance among under graduate medical students in a medical college of Western Uttar Pradesh

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Received: 18-09-2021 / Revised: 30-11-2021 / Accepted: 14-12-2021

Abstract

Introduction: Adverse drug reactions (ADRs) are adverse consequences of drug therapy. So, proper monitoring of ADRs is a necessity. Under reporting of ADRs is a common problem in Pharmacovigilance Programme of India. The active participation of health care professionals in the Pharmacovigilance Programme can improve the ADR reporting. In order to improve the reporting rate and successful running of Pharmacovigilance Programme and also prevent underreporting of ADRs, it is important to improve the knowledge, attitude of the healthcare professionals regarding ADR reporting and Pharmacovigilance. The best time to do it is during the under graduate study period. Hence, this study was designed to assess the impact of an education intervention on the knowledge and attitude of pharmacovigilance among undergraduate medical students of Subharti Medical College and Hospital Meerut, U.P, India. **Material and Methods:** This was prospective observational questionnaire based study. The study was a pre designed questionnaire based study which is structured to obtain information on the knowledge of the ADRs reporting, and the attitudes towards the reporting. The study tool was a modified pre designed questionnaire. A pre-post intervention questionnaire –based study was conducted among undergraduate medical students of Subharti medical college and hospital Meerut. A 16 item pretested pharmacovigilance questionnaire (ten and six questions for assessing knowledge and attitude respectively) was used before and after an educational intervention among 100 undergraduate medical students of Subharti Medical College and Hospital**.** For each correct answer a score of 1 was given whereas the scoring for wrong answer/ non attempted question was 0. The knowledge and attitude score for pre and post educational intervention were analyzed by Wilcoxon rank-sum test. The Software R version 2.6_2 was used to analyze pre and post intervention data. The assessment of knowledge and attitude mean scores before and after education intervention was done by paired t test. **Results:** A significant difference was found for most of the knowledge related questions(question 1 to 10 except 8) between before and after educational intervention ($p<0.001$). A significant difference was not found for question 8 (What does PvPI stands for) between before and after educational intervention ($P>0.05$). A significant difference was also found for most of the attitude related questions (question 11 to 16 except 12 and 15) between before and after educational intervention ($p<0.05$). A significant difference ($p<0.001$) was also found in assessment of knowledge mean scores before and after the educational intervention. Educational intervention had improved the knowledge significantly which was supported by an increase in knowledge mean score from 5.47 to 8.88 after the educational intervention. A significant difference ($p=0.001$) was also noted in assessment of attitude mean scores before and after the educational intervention. Educational intervention had also improved the attitude significantly which was supported by an increase in attitude mean score from 5.80 to 5.98 after the educational intervention. **Conclusion:** The present study findings showed that knowledge and attitude scores of pharmacovigilance were increased following an educational intervention among undergraduate medical students. The study findings also suggested that training on pharmacovigilance and adverse drug reactions tends to have a positive impact on knowledge and attitude among medical undergraduate students of Subharti Medical College and Hospital, Meerut, U.P, India.

Key words: Pharmacovigilance, pharmacovigilance programme of India (PvPI), adverse drug reactions (ADRs), attitude, knowledge, educational intervention.

Introduction

Adverse drug reaction (ADR) is defined as a response to a drug which is noxious and intended and which occurs at doses normally used in man for prophylaxsis, diagnosis or therapy of disease [1]. ADRs are the most important health care problem throughout the world affecting people with varying magnitudes and are the reason for both morbidity and mortality [2, 3].

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India is a developing country with large drug consuming population. Many diseases are prevalent so exposure to drugs is larger. ADRs have medical as well as economic consequences**.** ADRs are the cause of hospital admission in 3% to 6% of patients of all ages, while in elderly patients it is 3% to 24%. ADRs incidences have been reported to range from 5.9% to 22.3% of all emergency department admissions. Thus it is important that the drug treatment should be safe, efficacious and cost effective. It is also emerging as a clinical trial hub exposing larger population to newer drug therapies. It is the need of the hour to identify adverse drug reactions as early as possible and to prevent them if possible, to ensure the safety of the patient at reasonable cost**.** Adverse drug reactions (ADRs) are adverse consequences of drug therapy. ADRs are representing a major concern of health systems in terms of early recognition, proper management and prevention. Under reporting of Adverse Drug Reactions (ADRs) is a common problem in Pharmacovigilance programs. Pharmacovigilance is, "the science and the activities which

relate to the detection, assessment, understanding and the prevention of adverse effects or any other drug-related problems" [4]. An adverse drug reaction is associated with significantly prolonged length of stay, increased economic burden and almost 2-fold increased death. In addition to the human cost, ADRs having major impact on public health by imposing considerable economic burden on the society and already stretch health care system [5]. To improve the Pharmacovigilance activities in India, the Ministry of Health and Familty Welfare had initiated the National National Pharmacovigilance Programme (NPP) on first January 2005 which was further revived in July 2010 (Pharmacovigilance Programme India, PvPI). This programme is overseen by Central Drug Standard Control Organization (CDSCO), New Delhi [4]. The National Coordinating Centre of Pharmacovigilance Programme of India is located in Ghaziabad. The success of a Pharmacovigilance program depends upon active involvement of the healthcare professionals like Doctors, pharmacists & nurses. Reporting ADRs have immense responsibility towards patient care and strengthen the pharmacovigilance programs. Being the key healthcare professionals, providing information on suspected ADRs is as much a moral duty for the doctor as other aspects of patient care. An ongoing ADR monitoring and reporting program can provide benefits to the organization, doctors, nurses, pharmacists and also patients. The benefit includes increasing level of awareness regarding ADRs and to reduce morbidity and mortality of patient due to ADRs. ADR reporting does not currently appear to be considered a part of routine professional practice by health care professional. Poor perceptions of doctors about ADRs and risk management have contributed to high rate of ADR under-reporting in India. Underreporting has also been attributed to lack of time to doctor, misconceptions about spontaneous reporting and lack of information on how to report, where to report and a lack of availability of report forms, and also physicians' attitudes to ADRs. The Uppsala Monitoring Centre (UMC, WHO), Sweden, maintains the international database of the ADR reports. It has been estimated that only 6-10% of all the ADRs are reported [5]. One of the important factors of an efficient Pharmacovigilance system is contribution by health care professionals in the form of spontaneous reporting [4]. Pharmacovigilance Programme of India (PvPI) initiated ADR monitoring centres (AMC) to bring pharmacovigilance into practice and to enhance patient safety. AMCs includes Medical council of India (MCI) approved medical colleges and hospitals, private hospitals, autonomic institute (ICMR etc) and public health programs **[**6]. In order to improve the reporting rate and successful running Pharmacovigilance Programme and also prevent underreporting of ADRs, it is important to improve the knowledge, attitude and practices (KAP) of the healthcare professionals regarding ADR reporting and Pharmacovigilance. The best time to do it is probably during the under graduate and also post graduate education training of the doctors. But this is our duty as doctor to continue this activity during actual practicing.[5] Traditional methods of pharmacology teaching take place through didactic lectures and are more teacher-centered, with the main emphasis on learning facts about drugs [7]. The Medical Council of India (MCI) has recommended to teach ADR monitoring for undergraduate students, [8] in order to motivate the participation of health professionals in spontaneous reporting, it is necessary to design strategies that modify both intrinsic (knowledge, attitude and practices) and extrinsic (relationship between health professionals and their patients, the health system and the regulators) factors [9]. There is paucity of studies on awareness of reporting adverse drug reactions among the future medical practitioners. With this background, the main objective of the present study was designed to assess the impact of an education intervention on the knowledge and attitude of pharmacovigilance among undergraduate medical students of Subharti medical college and hospital Meerut, U.P, India.

Aims & Objectives

To evaluate the impact of an educational intervention on the knowledge and attitude of pharmacovigilance among undergraduate medical students of Subharti Medical College and Hospital Meerut, U.P, India.

Materials & Methods

This was prospective observational questionnaire based study. The study was conducted at Subharti Medical College and Hospital, Meerut, U.P. India. The approval for conducting the study was obtained from institutional ethics committee of this college. The study was conducted between June 2018 to July 2020. The study was conducted on 100 under graduate (MBBS 2nd professional course) medical students of Subharti Medical College and Hospital, Meerut. Informed consent of the participants was taken. The study was a pre designed questionnaire based study which is structured to obtain information on the knowledge of the ADRs reporting and the attitudes towards the ADRs reporting. The study tool was a modified pre designed questionnaire. A modified pre designed questionnaire was designed by following preceding studies [10, 11]. The questionnaire consists of total 16 questions. The pre test questionnaire was given to the participants and they have requested to complete the questionnaire in 30 minute. Any queries regarding questionnaire was solved at that time. After collecting the filled questionnaire, an extensive lecture based pharmacovigilance session of one hour was conducted following which a post test was conducted with new set of same questionnaire which was collected back after 30 minutes. If any clarification and extra time needed, have been provided. The questionnaire is divided in to 2 sections of knowledge (10 questions) and attitude (6 questions). The knowledge based ten questions are objective type while the questions of attitude based are "yes/no type". For each correct answer a score of 1 was given whereas the scoring for wrong answer/ non attempted question was 0. The total maximum score was 16. The completed questionnaire was collected from the participants and this filled questionnaire was analyzed. The knowledge and attitude score for pre and post educational intervention were analyzed by Wilcoxon rank-sum test. The Software R version 2.6_2 was used for the analysis of pre and post intervention data. The assessment of knowledge and attitude mean scores before and after education intervention was done by paired t test.

Statistical Analysis

The software R version 2.6_2 was used to analyze pre and post-intervention data. The knowledge and attitude score for pre and post educational intervention were analyzed by Wilcoxon rank-sum test. The Software R version 2.6_2 was used for the analysis of pre and post intervention data. The assessment of knowledge and attitude mean scores before and after education intervention was done by paired t test. p value <0.05 will be considered as statistically significant.

Results

About 100 undergraduate medical students (MBBS 2nd professional course) of subharti medical college were participated in the study. Table 1 shows the demographic characteristics of the participants. In this study among 100 participants, there are 53 male and 47 female participants. Mean age of participants is 19.68 years.(19.68±0.723) (Mean±SD).

Comparison of responses before and after the educational intervention on pharmacovigilance regarding knowledge related questions

Table 2 shows a comparison of responses before and after the educational intervention on pharmacovigilance regarding knowledge related questions. A significant difference was found for most of the knowledge questions (question 1 to 10 except 8) between before and after educational intervention (p<0.001). A significant difference was not found for question no 8.(What does PvPI stands for) between before and after educational intervention.(P>0.05).

Comparison of responses before and after the educational intervention on pharmacovigilance regarding attitude related questions

Table 3 shows a comparison of responses before and after the educational intervention on pharmacovigilance regarding attitude related questions. A significant difference was found for the most of the attitude questions (question 11 to 16 except 12 and 15) between before and after educational intervention ($p<0.05$).

Assessment of knowledge and attitude mean scores before and after an educational intervention

The comparison of knowledge and attitude mean scores before and after educational intervention was given in table 4 and figure 1. A significant difference ($p<0.001$) was found in knowledge scores. A significant difference was also found in attitude scores ($p=0.001$).

Table 1: Demographic details of the participants

Demographic details	Frequency (%)
Gender-	
Males	53 (53%)
Females	47 (47%)
Mean age (Years)	19.68
Age distribution (Years)	
19	47 (47%)
20	38 (38%)
21	15 (15%)

Table 2: Comparison of responses before and after the educational intervention on Pharmacovigilance regarding knowledge related questions

Knowledge based questions	Before lecture (Correct response %) among 100 UG students	After the didactic lecture (Correct response %) among 100 UG students	Z value	P value
1. Define ADR	77	99	-4.690	0.000
2. What is Pharmacovigilance	74	93	-4.146	0.000
. Which scale is most commonly used to establish the causality of an ADR	24	96	-8.485	0.000
4. Who can report an ADR	85	98	-3.357	0.001
5. Where is National Pharmacovigilance Centre in India located	44	95	-6.877	0.000
6. Where is UMC located	52	97	-6.564	0.000
7. Expand the acronym CDSCO	30	93	-7.697	0.000
8. What does PvPI stands for	94	99	-1.890	0.059
9. Is ADR reporting mandatory	06	24	-3.674	0.000
0. Are Adverse drug event and ADR same	61	94	-5.284	0.000

Table 3: Comparison of responses before and after the educational intervention on Pharmacovigilance regarding Attitude related questions

Attitude based questions	Before lecture (Yes/No %) among 100 UG students		After the didactic lecture (Yes/No %) among 100 UG students		Z value	P value
	Yes %	No %	Yes %	No %		
What do you think about ADR reporting? Is it necessary	95	05	99	01	-2.000	0.046
Do you think ADR reporting benefits both patients and doctors	98	02	100	00	-1.414	0.157
Should ADR reporting be included under Pharmacology practical	96	04	100	00	-2.000	0.046
Do you think medical students could play a role in ADR reporting	96	04	100	00	-2.000	0.046
Do you think discussion on ADR during clinical posting has any relevance	99	01	100	00	-1.000	0.317
16. Do you think box at all clinical department is helpful for proper reporting	94	06	99	01	-2.236	0.025

Table 4: Assessment of knowledge and attitude mean scores before and after the educational intervention (n=100)

		Mean+ S.D	Range	P value
Knowledge	Total score before educational intervention	5.47±1.62	2-9	0.000
	Total score After educational intervention	8.88±0.91	4-10	
Attitude	Total score before educational intervention	5.80±0.53	3-6	0.001
	Total score After educational intervention	5.98±0.14	5-6	

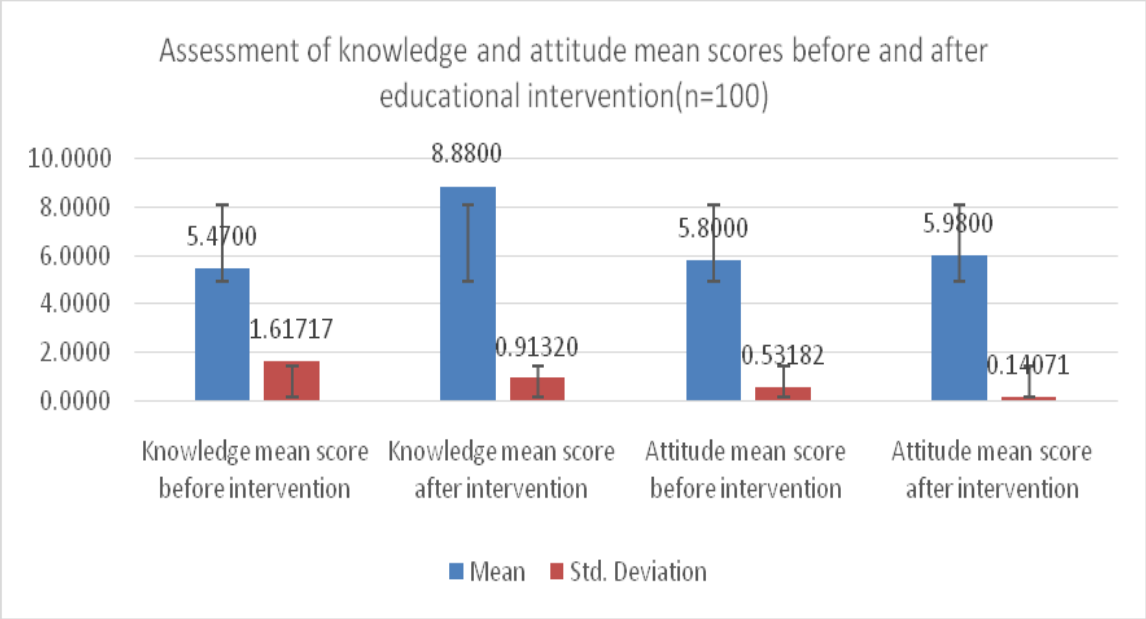

Fig. 1: Assessment of knowledge and attitude mean scores before and after educational intervention (n=100)

Discussion

The present study was conducted at pharmacology department of Subhart Medical College and Hospital Meerut. Since the year 2005, Department of Pharmacology of Subharti Medical College is engaged in Adverse drug reaction reporting under National Pharmacovigilance Programme of India and is one out of total 346 Adverse drug reaction Monitoring Centers (AMC). From July 2021 the department has also been nominated as Medical Device Adverse Reaction Monitoring Centre under Materiovigilance Program of India. The current study showed that male participants were higher than female.

There are only few studies which assessed the Pharmacovigilance knowledge and attitude after educational intervention among undergraduate medical students. This study was designed to assess the impact of educational intervention on pharmacovigilance knowledge and attitude among undergraduate medical students of Subharti Medical College and Hospital. The present study showed that majority of the undergraduate medical students of MBBS 2nd professional had knowledge and attitude.

The present study was in concordance with the study conducted by Joseph L.R et al [12]. This study revealed that significant difference was found for most of the knowledge questions between before and after educational intervention. The knowledge mean score of participants was found to be increased after the educational intervention. This study finding was found similar to several other studies conducted in Nepal [13-17] and in other countries [18-21].

This study also revealed that a significant difference was also found for most of the attitude questions between before and after intervention. The present study also revealed that an attitude score was found to be increased after the educational intervention. This study finding was found similar to other studies [22]. The knowledge regarding pharmacovigilance and adverse drug reactions is essential to all the undergraduate medical students and they have an important role in prevention, and monitoring of ADRs. The present study revealed that most of the study participants understood that ADRs reporting is essential to increase patient safety with medicines.

Before the educational intervention, only 77 % of participants knew about the definition of ADR. On post educational intervention analysis, 99 % of participants gave the correct answer. On before educational intervention analysis, 74% of participants gave correct answer regarding the definition of Pharmacovigilance. On post educational intervention analysis 93% of participants gave correct response about the definition of Pharmacovigilance. In the present study, on pre educational intervention analysis only 24% of participants gave the correct answer about the most commonly used scale to establish the causality of an ADR. On post educational intervention analysis 96% of participants gave the correct answer for the most commonly used scale to establish the causality of an ADR. Only 85% of participants gave correct answer about who can report an ADR before the educational intervention but after the intervention, 98% of participants gave the correct answer. In the beginning, only 44 % of participants knew about the correct location of national pharmacovigilance centre in India but after giving educational intervention , 95% of participants gave the correct answer about the location of national pharmacovigilance centre in India. Before the intervention, only 52% of participants have correct idea about the location of UMC but after the intervention, 97% of participants have correct idea about the location of UMC.

Before the intervention only 30% of participants gave the correct answer about the full form of CDSCO but after the intervention 93% of participants gave the correct answer. The National coordination Centre for proper monitoring of adverse drug reactions was set up at All India institute of medical science, New Delhi, in 2010 and later shifted to the Indian Pharmacopoeia Commission, district Ghaziabad, in 2011[23]. Reporting of Adverse drug reactions is an essential component of Pharmacovigilance programme of India. Spontaneous reportinng system is an important method of ADRs reporting[5].

Limitations

In our study we have included only MBBS 2nd professional course students as undergraduate participants. This study was single centric.

Conclusion

The present study findings showed that knowledge and attitude scores of pharmacovigilance were increased following an educational intervention among undergraduate medical students. The study findings also suggested that training on pharmacovigilance and adverse drug reactions tends to have a positive impact on knowledge and attitude among medical undergraduate students of Subharti Medical College and Hospital, Meerut, U.P, India.

Acknowledgements

The authors wish to thanks all the students for their contribution in active participation during the study and training.

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Conflict of Interest: Nil Source of support: Nil