

IMPACT OF EDUCATIONAL INTERVENTION ON KNOWLEDGE, ATTITUDE AND PRACTICE OF PHARMACOVIGILANCE AMONG MBBS STUDENTS IN A TEACHING INSTITUTION

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ABSTRACT

Introduction: In India, pharmacovigilance is still not a well versed topic among health care professionals and Adverse drug reaction (ADR) reporting is far behind rest of the world due to lack of knowledge and awareness. Training in pharmacovigilance of under-graduate students can play a vital role in improving this trend of under-reporting. Hence, this study was planned to assess the Knowledge, Attitude and Practice (KAP) among 2ND year MBBS students and subsequent change in these following a teaching session on pharmacovigilance. **Materials and Methods:** A cross-sectional questionnaire-based study was carried out among the 2ND Year MBBS students, coming for the lectures in the Department of Pharmacology of Government Medical College, Amritsar. Students were asked to fill a pre-designed structured KAP questionnaire consisting of 20 questions before and after training session. The comparison of Knowledge, Attitude and Practice among the students before and after the intervention was done using McNemar test. **Results:** A total of 161 students of 2nd year MBBS students of Government medical college Amritsar participated in pre test followed by educational intervention and post test. There was a significant improvement in overall response rate in knowledge and attitude among these students in KAP questionnaire following the teaching session on pharmacovigilance. However, improvement in practice towards ADR monitoring was not significant. **Conclusion:** Teaching session on pharmacovigilance improved the knowledge and inculcated positive attitude toward various aspects of adverse drug reaction reporting among MBBS students.

KEYWORDS: Pharmacovigilance, educational intervention, ADR reporting, Knowledge, Attitude and practice.

INTRODUCTION

Adverse Drug Reactions (ADRs) are a major global concern, responsible for 6.5 to 10.9 % of hospital admissions, 0.15 to 2.9 % mortality rates and have led to withdrawal of more than 75 drugs from the market due to safety concerns between 1969 and 2002.^[1,2] WHO defines ADR as 'a response to a drug which is noxious and unintended, and which occurs at a dose normally used in humans for prophylaxis, diagnosis, or therapy of disease, or for modification of physiological function'.^[3] ADRs can be kept into check by a well-organized pharmacovigilance system which deals with continuous evaluation and monitoring of ADRs. Pharmacovigilance is defined as 'the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem'.^[4] The event that prompted the world to demand for such an evaluation system was 'The Thalidomide disaster' in 1961, where over 10,000 children were born with serious congenital malformations because of thalidomide being prescribed to pregnant women to treat morning sickness.^[5] The aim of Pharmacovigilance programme of

India (PvPi) is to enhance patient safety by identifying drug safety signals, thus reducing clinical and economic impact of ADRs. National Pharmacovigilance Programme was launched in November 2004 by Central Drugs Standard Control Organization (CDSCO), Ministry of Health and Family Welfare, India, with the set up of 2 zonal, 5 regional and around 28 peripheral centres.^[6] The main purpose of this programme is to collect data, process and analyze it and use the inference to safeguard the health of Indian population.^[7] The main reasons behind the failure of pharmacovigilance system are: lack of funding, poor quality data and lack of knowledge, training and awareness among healthcare professionals.^[8,9] The effectiveness of PvPi is directly dependent on the active participation of health professionals. Therefore, there is an urgent need to create awareness among young doctors.^[10] Numerous studies have reported the awareness of pharmacovigilance among doctors and nurses, but there is lack of data with respect to undergraduate students. Therefore, the study was planned to evaluate the awareness towards pharmacovigilance and ADRs reporting system through

educational intervention because undergraduate students are the future doctors where they can observe and cultivate the reporting behaviour which can contribute to the patient safety.

MATERIAL AND METHOD

Study setting: A cross-sectional Knowledge, Attitude, Practice (KAP) questionnaire based study was carried out in the Department of Pharmacology of Government Medical College, Amritsar, from September – November 2019.

Study population: A total of 161 students of 2ND Year MBBS coming for the practical lectures in pharmacology department were selected. The students who were not willing to participate in the study and the ones who were on leave were excluded.

Study tools: For the purpose of the study, a standard KAP structured questionnaire with 20 questions was adapted from the literature and two-step validation process was done to achieve clarity and accuracy of the content. Initially, there were 28 questions which were later on reduced to 20 questions after the final validation process. In step 1 of validation process, the questionnaire was given to two faculty members and 1 senior resident, who are in the institutional pharmacovigilance committee and have experience in this field. They were asked to evaluate the questionnaire in terms of coherence, relevance and accuracy. After their feedback, 6 questions were eliminated on account of being irrelevant and complex to understand. In the second validation step, a pilot study was done on 10 2nd year MBBS students who didn't participate in the actual study. After this, two more questions were omitted which they found hard to comprehend and 2 questions were rephrased. The final KAP questionnaire consisted of 20 questions (7 for knowledge, 7 for attitude and 6 for practice). Suggestions on ways to improve the ADR reporting were also asked in last section of questionnaire.

Data collection- After explaining the purpose of the study, a pre-KAP questionnaire was handed over to the students. Duration of 20 minutes was allocated for filling the answers. A score of 1 was given for each correct answer or positive response and a score of 0 was allocated for wrong, un-attempted answer or negative response. After the completion of the pre-KAP questionnaire, a 3-day interactive teaching session was done. On day 1, a power point presentation was given regarding the introduction and history of pharmacovigilance, Pharmacovigilance Programme of India (Pvpi), adverse drug reactions (types, incidence and classification), role of health care professionals in ADR reporting and effect of ADR monitoring on patient safety. On day 2, pictures of common ADR cases were shown and the suspected drugs were discussed with the students. Then, all the students were divided into 5 groups. Each group was given an ADR form and 5 hypothetical clinical scenarios were provided. Students

were introduced to different sections of ADR form and made to fill these forms as per given clinical scenarios. Later on these forms were discussed and corrected by the investigators. On day 3, students were sensitized to different causality assessment scales and given hands on training in entering the ADR data in vigiflow. This whole intervention went on for 4 weeks in 4 batches (with an average of 40 students per batch) during the practical classes of the students. The intervention was specially designed on the terms of competency based medical education (CBME) in order sensitize them to new curriculum. The impact of intervention was assessed with the help of post KAP questionnaire, being distributed to all students who had undergone the pre-test, after a period of two months. For ensuring the response rate, all the students were provided the questionnaire personally and requested to fill it within 20 minutes on the same day and the duly filled questionnaire were collected.

Data analysis: The filled KAP questionnaires were analyzed as per the study objectives. The data obtained was entered in Microsoft excel spread sheet and was analyzed using SPSS version 23.0.1. The normality of the data was checked using Kolmogorov-Smirnov Test. The data was represented in the form of percentages. The comparison of Knowledge, Attitude and Practice among the students before and after the session was done using McNemar test. Overall score of KAP study calculated before and after the intervention were also compared using Wilcoxon sign ranked test. The level of statistical significance was set at p value <0.05.

RESULTS

A total of 161 MBBS 2nd year students of Government Medical College, Amritsar participated in pre-test followed by an interactive teaching session and post-test.

Knowledge towards Pharmacovigilance Pre and Post interactive teaching session

Table-1 compares the knowledge of the students before and after the intervention based on 7 questions mentioned in section I of the questionnaire. After the interactive teaching session, there was a significant improvement in knowledge with respect to definition of pharmacovigilance (83% vs 91%, p value <0.05), who can report ADR (74% vs 97%, p value <0.001) and International organization related to ADR reporting (13% vs 78%, p value <0.001). However, more students knew the definition of ADR, type of ADRs to report, Indian regulatory body monitoring PvPi and full form of CDSCO in the post-test group, but no significant difference (p value >0.05) was seen compared to pre-test group.

Attitude towards ADR reporting Pre and Post interactive teaching session

The attitude of students before and after the intervention is compared in Table 2 which consisted of 7 questions about the ADR reporting in section 2 of the

questionnaire. There was a significant difference (pre vs post p value < 0.05) in response to questions such as whether health care providers have any professional obligation towards ADR reporting (64% vs 85%), awareness of the ADR monitoring center in the institution (15% vs 73 %) and the online portal for ADR reporting (20 % vs 70%). Whereas, majority of students opined (both pre and post test) that reporting ADR is important (98% vs 98% p value= 1.00), pharmacovigilance should be taught to health care providers (98% vs 97%, p value=0.68). Further they felt that ADR reporting is necessary for patient safety (98% vs 95%, p value=0.10) and all type of ADR whether serious or not should be reported (86% vs 81, p value=0.37).

Practice towards ADR reporting Pre and Post interactive teaching session

The comparison of practice component of KAP questionnaire among students before and after the intervention is done in Table 3 which was evaluated with a set of 6 questions in section 3. There was a significant difference (p value < 0.05) in response to information

about whether they have filled any ADR form (8% vs 80%) and willingness to report ADR in future (78% vs 90%). However, most of students didn't come across any new ADR case (10%) and drug alerts in ward postings (35%) during intervention period. There was no significant change in ADR reporting and frequency of visits to AMC (p value> 0.05).

Overall mean score of KAP study pre-session was 10.66 ±2.04 and post session 14.22± 1.94 which was statistically significant (p value <0.05).

Section 4 of the questionnaire was designed to ask suggestions for ways to increase ADR reporting. It was left un-attempted by majority of students. Few of the proposals suggested were: 1) Frequent sensitization through CMEs and workshops of all related to health care to foster ADR reporting culture. 2) Hands on training on filling of ADR forms and uploading the same online. 3) Digital Smartphone apps for ADR reporting. 4) ADR reporting should be inculcated in the undergraduate curriculum.

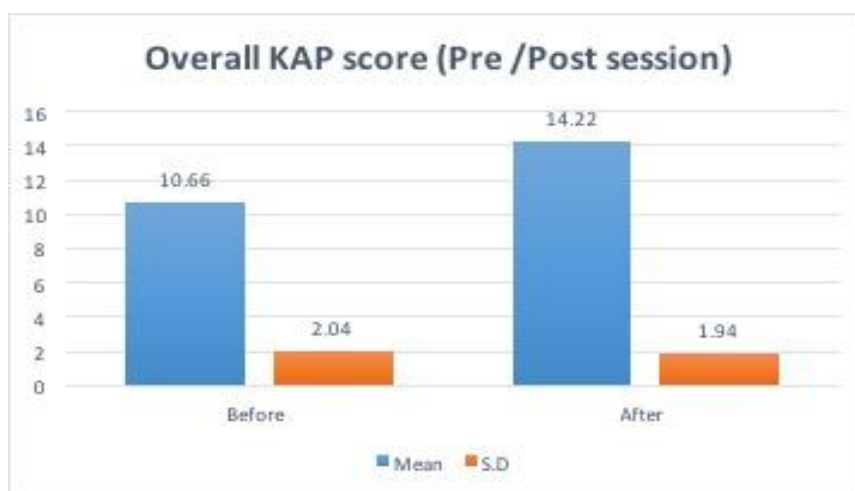


Table 1: Assessment of knowledge towards pharmacovigilance pre- and post- interactive teaching session.

Serial Number	Pharmacovigilance Knowledge related questions	Pretest correct response (n= 161)	Post test correct response (n=161)	P value
1	What does ADR (adverse drug reaction) mean?	69% (111)	76% (12)	0.25
2	Pharmacovigilance is defined as	83% (133)	91% (145)	0.05*
3	Pharmacovigilance includes ADRs related to	63% (101)	72% (115)	0.13
4	Who can report ADR?	74% (119)	97% (155)	0.001*
5	Which regulatory body is monitoring the Pharmacovigilance Programme in India?	50% (81)	62% (100)	0.61
6	International organization responsible for ADR monitoring is	13% (21)	78% (125)	0.001*
7	What is the full form of CDSCO?	89% (143)	92% (147)	0.55

*p<0.05, calculated by McNemar test

Table 2: Assessment of attitude towards adverse drug reaction reporting pre- and post- interactive teaching session.

Serial number	Pharmacovigilance attitude related questions	Pretest correct answer (n=161)	Post test correct answer (n=161)	P value
1	Is reporting of ADRs important?	98% (156)	98% (157)	1.00
2	Should health care providers be taught about pharmacovigilance activities?	97% (155)	98% (157)	0.68
3	Do you think ADR reporting help in patient safety in long run?	95% (151)	98% (156)	0.10
4	Do you think ADR reporting is professional obligation of all related to health care?	64% (102)	85% (136)	0.001*
5	Only serious and unexpected ADRs should be reported?	86% (137)	81% (130)	0.37
6	Do you know the location of ADR monitoring center in your institution?	15% (24)	73% (116)	0.001*
7	Do you know about the online portal site for reporting ADRs?	20% (33)	70% (112)	0.001*

*p value <0.05 is calculated by McNemar test

Table 3: Assessment of practice towards adverse drug reaction reporting pre- and post- interactive teaching session.

Serial number	Pharmacovigilance Practice related questions	Pre test correct answer (n=161)	Post test correct answer (n=161)	P value
1	Have you seen any ADR case in your ward posting?	10% (17)	10% (17)	1.00
2	Have you come across 'drug alerts'?	35% (56)	35% (57)	1.00
3	Do you know how to fill an ADR form?	8% (14)	80% (128)	0.001*
4	Have you ever reported any case of ADR?	5% (8)	10% (17)	0.10
5	Have you visited any ADR monitoring center?	6% (10)	15% (25)	0.07
6	Are you willing to do ADR reporting?	78% (125)	90% (144)	0.001*

*p value <0.05 is calculated by McNemar test

DISCUSSION

Pharmacovigilance is an integral part of holistic approach towards health care.. Spontaneous reporting of ADR is vital for the success of pharmacovigilance program. This is one of pioneer studies where educational intervention was given on the lines of new curriculum (CBME).

The present KAP study was done on 2nd prof. undergraduate students in the department of Pharmacology to test their knowledge, attitude and practice towards pharmacovigilance before and after an interactive teaching session.

In our study, before the teaching session, most of students were aware about definition of ADR, what type of ADRs to report and definition of pharmacovigilance. They lacked the knowledge related to Pharmacovigilance Programme of India and regulatory bodies associated with it. The results were in accordance to study done by

Datta D et al.^[10] on medical post-graduates where they had reasonable knowledge about the definition and purpose of pharmacovigilance. However, Vora et al.^[11] showed a contrasting results where undergraduates students have average to poor knowledge to pharmacovigilance. Also a study conducted by Gupta et al.^[12] reported very few doctors were aware of Pharmacovigilance Programme of India. This was also supported by a study conducted by Madhan Ramesh et al.^[13] which stated that doctors were less aware of the national and international pharmacovigilance programs.

In our study, majority students agreed that reporting an ADR is important and it helps in patient safety in long run but they were unaware of the online portal site for reporting ADRs and location of AMC in the institution before the intervention. These results were in accordance to study done by Thomas et al.^[14] in which only 11% respondents were aware of the regional center for ADR reporting. Also 98% subjects felt that reporting an ADR

is the duty of health care professional. It can be concluded that students had the background information, but they lacked the practical application of that knowledge.

Other studies have also shown similar attitude where it was found that most common discouraging factors for ADR reporting in doctors was the lack of knowledge on where to report, non – availability of reporting forms,(41.6%), previously known ADRs (38.32%), inability to diagnose ADR (34.99%), concern of extra work (31.6%), busy practice (29.99%), non-remuneration (23.3%) and feeling that not sending one report may not contribute a lot to patient care (13.32%).^[15,16]

Before the intervention, there was huge lacuna in spontaneous reporting of an ADR, practice of filling an ADR form and visit to ADR monitoring center. This deficiency can be attributed to the lack of training of the students how and where to report an ADR. This low response rate was similar to some other studies used for comparison in this paper that involved medical practitioners.^[17,18]

A survey conducted by Chatterjee S et al^[19] which included 138 clinicians observed good knowledge but poor attitude and practice with regard to ADR reporting. Their study also concluded that there is a need to spread awareness of pharmacovigilance by including it in medical teaching and training curriculum. An educational interventional program in pharmacovigilance study of Li Q, Zhang et al^[20] showed that educational intervention improved awareness of knowledge, attitudes, practice of healthcare professionals towards practice of pharmacovigilance. Questionnaire based study done by Ranjan et al.^[21] showed students have poor knowledge and practice but have positive attitude towards ADR reporting.

The most encouraging part of the study was that 90% of students were willing to report the ADR after the intervention. But, there was not much improvement in the frequency of reporting an ADR during the study period, which was in contrast to the study where there was five-fold increase in ADR reporting.^[22,23]

The main limitation of the present study was the inclusion of a relatively small number of students. Also the findings cannot be generalized as the study was restricted to just MBBS 2nd prof. students. The time gap between the two tests was also not sufficient to analyze the difference in practice of ADR reporting. More studies with large pool of subjects (physicians, nurses, pharmacists) and long duration can be done in future.

CONCLUSION

The present study has shown that following an interactive educational intervention, the knowledge and attitude toward the ADR reporting seems to have

improved. The importance of sensitizing the students is that they can form a bridge between the ADR reporting center and clinical departments as lack of time and patient load was one of the main reason towards underreporting. Majority of students were aware about the ADR reporting but they were not trained to practically apply that knowledge clinically. The actual frequency of ADR reporting did not improve. In our opinion, awareness should be generated regarding the purpose and usefulness of ADR reporting among doctors through CMEs and workshops. ADR reporting can be further increased by improving access to ADR reporting forms, using user-friendly methods such as electronic reporting targeting especially the junior healthcare professionals.

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