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The need for a focused module on adverse drug reactions monitoring for future prescribers

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Abstract

Purpose: Adverse drug reactions are responsible for morbidity and mortality globally. Inspite of having the Phamacovigilance Programme in India, under-reporting of ADRs is still extensive. The success of the pharmacovigilance depends upon the knowledge and active participation of healthcare professionals. It may therefore be important to raise awareness of pharmacovigilance in their formative years through a dedicated educational module. For this purpose, a study was designed with the following objectives:

Objectives: 1. To evaluate the knowledge and attitude of medical and dental students towards pharmacovigilance.

2. To determine the need for a specific module on pharmacovigilance in undergraduate teaching.

3. To assess the effectiveness of the module on changing the knowledge and attitude about pharmacovigilance.

Method: A cross-sectional questionnaire-based study was conducted on pharmacology going medical and dental students for a period of 6 months. A structured questionnaire consisting of 20 questions was used for pre-test. A pharmacovigilance module was developed and imparted to the participants. After a gap of 2 weeks a post-test was conducted with the same questionnaire.

Results: Overall knowledge of the pre-test and post-test participants was 51.43% and 55.97% respectively. The overall knowledge difference before and after module implementation was statistically significant. The study participants in both pre-test and post-test had good attitude towards pharmacovigilance but there was no change in attitude.

Conclusion: The focused module on adverse drug reactions monitoring was effective in improving the knowledge and attitude of the study participants. Early sensitization of undergraduate students about pharmacovigilance may promote rational and safe use of medicines and inculcate ADR reporting as part of their clinical practice in future.

Keywords: pharmacovigilance, learning, side effects, medicines, doctors

Introduction

An ADR is defined by WHO as any noxious, inadvertent and undesirable drug effect, which can occur at doses routinely used in man.[1] Adverse drug reactions (ADRs) can affect all age groups. They are responsible for morbidity and mortality globally.[2] ADRs can extend hospital stay and escalate the treatment cost. The incidence of ADRs resulting in hospital admissions varies between 0.2 to 41.3% worldwide, however 28.9% of them can be prevented.[3] Even though the Pharmacovigilance Programme of India was initiated in July 2010, under-reporting of ADRs is still very widespread.[4] According to Uppsala Monitoring Centre (WHO), Sweden, only 6-10% of ADRs worldwide are reported.[5] This under-reporting is a matter of concern and some of the reasons for this include the lack of knowledge about Pharma co-vigilance, poor awareness about the need for ADR monitoring and training in this area among healthcare professionals, unfamiliarity with the pharmacovigilance system, poor ADR-reporting skills and negative attitudes such as ignorance, fear of legal liability.[6,7]

The success of the pharmacovigilance Programme depends upon the knowledge and active participation of healthcare professionals. Therefore, it is imperative that the future healthcare professionals need to acquire early knowledge and competency for pharmacovigilance competencies so that they understand the need as well as practice ADR reporting in daily work which can in turn encourage safe prescribing.[8] Currently the undergraduate curriculum does not include pharmacovigilance in detail and students are not actively involved in reporting ADRs. As medical and dental students will be future prescribers, it would be important to make them aware of the need for ADR monitoring as well as to determine the need for a focused module in their teaching on this topic. Hence, a study was done with the following objectives:

1. To evaluate the knowledge and attitude of medical and dental students towards pharmacovigilance.
2. Based on the above, to determine the need for a specific module on pharmacovigilance in undergraduate teaching.
3. To assess the effectiveness of the module on changing the knowledge and attitude about pharmacovigilance.

Our study is different from other studies as it evaluated the knowledge and attitude of future prescribers before and after an educational module on Pharmacovigilance.

Method

The unique feature of our study methodology was that a pharmacovigilance module was developed based on the inputs from pretest questionnaire to improve the knowledge and attitude of the participants. A post-test was conducted to evaluate the effectiveness of the module.

Setting: The study was conducted at Pushpagiri Institute of Medical Sciences and Research Centre, Tiruvalla, India. The hospital is more than 50 years old, and caters to a wide variety of patients from the district and beyond from primary to tertiary healthcare. The study was conducted after obtaining approval from Institutional Ethics Committee.

Study design: A cross-sectional study was conducted on pharmacology going medical and dental students of the institution for a period of 6 months. All the students who gave their consent were included in the study. The process during the study period included the following steps:

A. A structured pretested questionnaire was designed and used to collect demographic details and assess the knowledge and attitude of the students towards

Pharmacovigilance and ADR monitoring. The questionnaire contained 20 questions, with 10 questions each to assess knowledge and attitude. In addition, space was provided to give suggestions and other additional information. Once completed, the questionnaires were collected, analyzed and the results tabulated and interpreted.

B. Based on the information gained from the questionnaire, a Pharmacovigilance module was developed keeping in mind the areas where students had less knowledge. The module was taught to the participants in lecture format using powerpoint presentation as a visual aid. The module focused on the definition and scope of pharmacovigilance, Pharmacovigilance programme of India, the stakeholders and the details of ADR reporting form.

C. After a gap of 2 weeks, a post-test with same questionnaire was done. The data from post-test was tabulated and interpreted. The results of the pretest and post-test were compared for any change in knowledge and attitude of the participants.

Participants: There were 225 participants who were included in the study. 14 participants were absent on the day of post-test. Hence, only the information from 211 participants were compared. Participants were recruited after an informed consent process.

Statistical analysis: The data from the pretest and post-test questionnaires was analysed using Statistical Package for Social Sciences (SPSS) version 20. Paired t tests were used to compare knowledge of participants before and after the module. P value < 0.05 was considered significant.

Results

Our study evaluated the knowledge and attitude of the future prescribers adverse drug reaction monitoring before and after implementation of Pharmacovigilance module.

Demographic details: In the present study, there were 225 participants in pre-test and 211 participants in post-test. Among the 225 pre-test participants, 56 participants were male and 169 female students. The mean age of the participants was 19.87 years. There were 179 medical and 46 dental students. Among the 211 post-test participants, there were 47 male and 164 female students. The mean age was 19.91 years. There were 172 medical and 39 dental students. (Table 1)

Table 1: Demographic details of the participants:

	Pre-test (n = 225)	Post-test (n = 211)
1. Gender		
Male	56 (24.89%)	47 (22.27%)
Female	169 (75.11%)	164 (77.73%)
2. Mean age (years)	19.87	19.91
3. Professional status		
Medical students	179 (79.56%)	172 (81.52%)
Dental students	46 (20.44%)	39 (18.48%)

Evaluation of knowledge of pharmacovigilance before and after module implementation

Pre-test: Overall knowledge of the medical students was 51.39% and of dental students was 51.55%.

Post-test: Overall knowledge of the medical students was 74.98% and of dental students was 56.56%.

The overall Knowledge difference before and after module implementation was statistically significant for medical students (P value < 0.05). After module implementation, the medical students showed significant improvement in their knowledge about the timeline of serious adverse event reporting, the year in which The Pharmacovigilance programme of India was started and the International body to which India sends its ADR reports ($p < 0.05$). (Table 2)

There was no significant difference in the overall knowledge score of dental students after module implementation. However, they showed significant improvement in their knowledge about the areas for which ADR reporting should be done and who benefits from it ($p < 0.05$). (Table 2)

Table 2: Pharmacovigilance related knowledge of the participants.

	Medical students		Dental students	
Knowledge related questions	Pretest (correct response %)	Post-test (correct response %)	Pretest (correct response %)	Post-test (correct response %)
1.Pharmacovigilance definition	154 (86.03)	141 (81.98)	42 (91.3)	33 (84.62)
2. Primary purpose of pharmacovigilance	149 (83.24)	137 (79.65)	38 (82.6)	29 (74.35)
3. Who can report adverse drug reactions?	111.25 (62.15)	107.25 (62.35)	23.5 (51.1)	24.5 (62.82)
4. ADR reporting should be done for?	78.75 (43.99)	81.25 (47.24)	16.25 (35.3)	19.75 (50.64)*
5. Who benefits from ADR reporting?	118.5 (66.20)	73.95 (42.99)	15.9 (34.6)	16.85 (43.2)*
6. Components of ADR reporting form	125.5 (70.11)	122.75 (71.37)	30.5 (66.3)	23.5 (60.25)
7. Serious adverse event reporting timeline	6 (3.35)	21 (12.20)*	2 (4.3)	3 (7.69)
8. In which year was The Pharmacovigilance Programme of India started	75 (41.90)	91 (52.91)*	17 (36.9)	22 (56.41)

9. In India, which regulatory body is responsible for monitoring ADRs	120 (67.04)	120 (69.77)	42 (91.3)	34 (87.17)
10. To which international body, does India send its ADR reports	25 (13.96)	66 (38.37)*	10 (21.7)	15 38.46)

*Indicates $p < 0.05$

Evaluation of Attitude towards pharmacovigilance before and after module implementation

Out of 10 questions used to assess the attitude of the participants, 3 were in the form of multiple choice questions (Q1 to Q3) and remaining 7 questions (Q4 – Q10) had 5 point Likert scale. There was no significant difference in the attitude of the participants after module implementation. (Table 3)

Table 3: Pharmacovigilance related attitude of the participants

	Medical students		Dental students	
Attitude related questions	Pretest (correct response %)	Post-test (correct response %)	Pretest (correct response %)	Post-test (correct response %)
1.What type of ADR reporting system do you think is essential?	105 (58.66)	103 (59.88)	24 (52.17)	16 (41.03)
2. Which of the following pharmaceutical products do you think should be monitored for ADRs?	108 (60.34)	100.75 (58.58)	20 (43.48)	20 (51.28)
3. How can one benefit from ADR reporting?	158.25 (88.41)	144 (83.72)	33 (71.74)	30 (76.92)
	(No. of participants who agreed %)	(No. of participants who agreed %)	(No. of participants who agreed %)	(No. of participants who agreed %)
4. Do you think reporting of ADR is needed?	152 (84.91)	127 (73.84)	45 (97.82)	38 (97.43)
5. Do you think ADR reporting is an obligation for healthcare professionals?	116 (64.8)	115 (66.86)	21 (45.65)	20 (51.29)
6. Do you think ADR reporting damages professional image?	138 (77.08)	121 (70.35)	32 (69.56)	33 (84.6)

7. Should an ADR monitoring centre be established in every hospital?	160 (89.38)	157 (91.26)	42 (91.31)	35 (89.74)
8. Is there a need for availability of information on ADRs and their management strategies within a hospital?	166 (92.74)	162 (94.19)	43 (93.48)	36 (92.31)
9. Do you think Pharmacovigilance should be taught to healthcare professionals?	171 (95.53)	157 (91.28)	43 (93.48)	35 (89.75)
10. Do you think conducting workshops/modules on Pharmacovigilance would improve ADR reporting?	177 (98.88)	160 (93.03)	39 (84.78)	37 (94.87)

Discussion

Pharmacovigilance plays an integral role in the safe use of medicines. However, under-reporting of adverse drug reactions is a detriment to the success of pharmacovigilance. In order to improve the reporting of ADRs, awareness about pharmacovigilance has to be created among the health care professionals. Various studies have been conducted to assess the knowledge, attitude and practice of health care professionals[9-13] but studies on medical and dental students are minimal.[14,15] Since these students will be future prescribers, they can play a dynamic role in ADR monitoring. As it is important to introduce them into the concept of pharmacovigilance and sensitize them to the need to be 'pharmacovigilant' throughout their prescribing career, having specific modules on pharmacovigilance are the need of the hour. This study therefore assessed whether knowledge and attitude improved by administering specific modules on pharmacovigilance.

Before administering the module, the knowledge and attitude of medical and dental students about adverse drug reaction monitoring and pharmacovigilance was assessed. In the pretest, overall knowledge of the medical students was 51.39% and of dental students was 51.55%. In studies by Meher et al[14] and Vora MB et al[15] the participants had similar knowledge. The medical students showed an improvement in their overall Knowledge following the module implementation (P value < 0.05). Hence, overall, the pharmacovigilance module was very effective in improving the knowledge of these students about ADR monitoring. Lack of knowledge of ADR reporting is also one of the major reasons for under-reporting according to numerous studies.[16,17] Therefore it may be imperative to include pharmacovigilance in detail in the undergraduate curriculum and encourage them to participate actively in adverse drug reaction monitoring.

Knowledge assessment before the module was imparted revealed some areas of knowledge weakness among the students. Most of the pre-test participants were not aware that pharmacovigilance encompasses ADRs due

to all systems of medicine, vaccines and even medical devices. They also believed that ADRs due to new drugs and rare ADRs only should be reported. These outcomes were comparable to the study by Gupta P et al.[18] This perception was altered after the pharmacovigilance module was imparted and vast majority of post-test participants had correct knowledge regarding these aspects of pharmacovigilance. It is essential to spread awareness regarding these details because the healthcare professionals should know that all suspected ADRs, drug interactions, congenital anomalies due to drugs also need to be reported promptly. This may prevent under-reporting of ADRs, improve drug safety and promote rational use of medicine.

Majority of pre-test and post-test participants agreed that it is essential to report an ADR and it is a professional obligation for them. The study participants also agreed that Pharmacovigilance should be taught to healthcare professionals and conducting periodic workshops and training of adverse drug reaction monitoring would improve the ADR reporting. Similar findings are reported by Upadhyaya HB et al[19] and Gupta SK et al.[20] A positive correlation between training of pharmacovigilance and ADR reporting was re-emphasized by Gupta SK et al.[20] These study outcomes emphasise the need for early sensitization of undergraduate students about Phamacovigilance and training in Pharmacovigilance at frequent intervals for healthcare professionals. Early sensitization about pharmacovigilance may improve the knowledge of healthcare professionals and develop a positive attitude towards ADR monitoring and inculcate the practice of pharmacovigilance as an integral part of their patient care.

Most of the study participants including pre-test and post-test agreed that information on ADRs and their management strategies should be available within a hospital. It is important to provide information about the events to be watched for and reported and provide solutions to the expected hurdles in ADR reporting. These objectives may be achieved by establishing a dedicated pharmacovigilance centre in hospitals which can offer information about adverse drug reactions to be expected with drug use, possible drug interactions and food-drug interactions, the comorbidities that can result in ADRs, treatment approaches in case there is an ADR. These measures may help improve the reporting of ADRs encountered in the hospital. Along with theoretic knowledge on Pharmacovigilance, practical training of undergraduate students is also essential. This can be achieved by a visit to the Pharmacovigilance center or by posting them to a Pharmacovigilance center to get first hand experience in the type of cases, nuances of reporting and data entry.

Strengths and Limitations of the Study

Our study is one among the few studies done to assess the knowledge and attitude of medical and dental students about pharmacovigilance. Our study also assessed the effectiveness of pharmacovigilance module in improving the knowledge and attitude of the participants. Since the medical and dental students will be future prescribers, it is important to train them in pharmacovigilance so that they will contribute actively to ADR monitoring and reporting.

The major limitation of this study is that since the participants are students and not actively involved in pharmacovigilance, we could not assess the practice based aspects of pharmacovigilance. Another limitation was recall bias. This can be overcome by providing longer interval between imparting module and post-test.

Conclusion

The knowledge of pre-test participants about pharmacovigilance was not optimal. The study participants, however, had good attitude towards pharmacovigilance. The educational intervention in the form of pharmacovigilance module improved the knowledge and attitude of the participants effectively. The participants also emphasized the need for inclusion of pharmacovigilance in the undergraduate curriculum and training sessions on ADR reporting. They also opined that establishing an information centre in the hospital about ADRs and their management strategies would be helpful. Our study highlighted that early sensitization of undergraduate students about pharmacovigilance may promote rational and safe use of medicines and inculcate ADR reporting as part of their clinical practice in future.

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