Impact of educational intervention on the knowledge, attitude, and practice of pharmacovigilance among postgraduates of a tertiary care center, Kanchipuram, Tamil Nadu, India

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Original Article

Introduction: Prescription of drugs should always be done in a judicious manner and with a satisfactory risk/benefit ratio. Pharmacotherapeutic agents are one of the important causes of adverse effects starting from mere inconvenience to permanent disability and death. Studies suggest that about 0.2%–24% of patients with adverse drug reactions (ADRs) are subjected to hospital admission in India as well as in several highly developed industrialized countries. India contributes below 1% in terms of ADR reporting against the world rate of 5%. To enhance the reporting rate, it is important to improve the knowledge, attitude, and practice (KAP) of all the health-care professionals with regard to the ADR reporting and the pharmacovigilance (PV).

Aim: The aim of the study was to evaluate the basic KAP of the postgraduate (PG) students at Meenakshi Medical College and Hospital, Enathur, Kanchipuram, Tamilnadu, India, regarding ADR monitoring and PV.

Materials and Methods: This was a before and after comparison study with an educational intervention. A knowledge-, attitude-, and practice-based questionnaire on ADR reporting and PV program was prepared and administrated.

Results: Participants had good theoretical knowledge regarding PV, but their attitudes and practical knowledge increased significantly after an educational intervention. The overall scores observed between pretest and posttest were found to be statistically significant.

Conclusion: Educational intervention had proven to be an effective tool in improving the KAP of PV in the present study. Lack of motivation and training toward ADR reporting discourages PGs from reporting. Revisions are needed to include the clinical application of PV in the present academic curriculum. Ensuring a better safety profile for drugs can be done only through PV.

Keywords: Adverse drug reaction, educational intervention, pharmacovigilance, postgraduates, questionnaire

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INTRODUCTION

None of the therapeutic drugs are absolutely devoid of adverse effects. Prescription of drugs should always be done in a judicious manner and with a satisfactory risk/benefit ratio. The World Health Organization (WHO) defined “adverse drug reactions (ADRs)” as any noxious, unintended, and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or cure of a disease. ADRs are already established reasons for mortality and morbidity worldwide. Pharmacotherapeutic agents are now the cause of serious adverse reactions ranging from mere inconvenience to permanent disability and death. Studies suggest that about 0.2%–24% of patients with ADRs are subjected to hospital admission in India as well as in several highly developed industrialized countries. ADR also has a significant impact on cost in the health-care system.

Ministry of Health and Family Welfare, Government of India, had initiated the National Pharmacovigilance (PV) Program. The main reason behind initiating such a program was to safeguard the health of the Indian population by ensuring that the benefit of the use of medicine outweighs the risks associated with its use and to provide information regarding the safety of medicines to health-care professionals and the public, recommend the regulatory authorities for intervention, and to create signals (possible causal relationship between an adverse event and a drug). India contributes below 1% in terms of ADR reporting against the world rate of 5%.

The success of PV program in India merely depends on the active involvement of the health-care professionals such as doctors, pharmacists, and nurses. It is important for health-care professionals to know how to report and where to report an ADR.

PV studies are emerging nowadays due to the advent of new drugs and a quite number of drugs withdrawn due to ADRs. Although Pharmacovigilance Programme of India (PvPI) contributes to Uppsala Monitoring Centre database due to the lack of vibrant ADR monitoring and reporting system among the health-care workers, the reports contributed by India are very little only. To enhance the reporting rate, it is important to improve the knowledge, attitude, and practice (KAP) of all the health-care professionals, especially the postgraduates (PGs) with regard to the ADR reporting and PV. PGs play a prime role in treating the patients in any medical college. They are the workforce of a teaching institute. PGs of any discipline would be the primary point of contact for any ADR encountered by the patient.

This study was such a step taken to evaluate the basic knowledge attitude and practice of the PG students at Meenakshi Medical College and Hospital, Enathur, Kanchipuram, Tamil Nadu, India, regarding ADR monitoring and PV.

MATERIALS AND METHODS

Study design

This was a before and after comparison study with an educational intervention done at Meenakshi Medical College Hospital and Research Institute (MMCH and RI), Enathur, Kanchipuram, Tamil Nadu, on July 25, 2019. Institutional ethics committee approval was obtained. Informed consent was obtained from all participants. A convenient sampling method was used to enroll the PGs belonging to different disciplines.

A knowledge-, attitude-, and practice-based questionnaire on ADR reporting and PV program was prepared. It was peer reviewed by the expert faculties of the PV committee of our institute. The questionnaire was semi-structured, predesigned, pretested, and validated using the research tool for data collection. Few changes were made as per the study requirement and the questionnaire had finally 20 questions. Question numbers 1–10 was knowledge based, questions 11–15 were pertaining to attitude, and question numbers 16–20 were practice based. Pretest was conducted for all the enrolled PGs 30 min prior to the educational intervention.

Intervention

An interactive educational intervention was conveyed to all the participants through the presentation on the definition of PV, classification of ADRs, causality assessment, seriousness and severity of ADRs, WHO online database for reporting ADRs, who can report an ADR, and how to report a suspected ADR, followed by economic and epidemiological importance of reporting ADRs and its effect on patient safety. The session was conducted by experts in PV. The practical part of the intervention included documentation of ADRs using suspected ADR reporting forms provided by PvPI and hands-on training in assessing the causality of ADRs through the WHO causality assessment scale and Naranjo’s scale. Posttest was conducted for all participants after the educational session with the same questionnaire.

Statistical analysis

The pretest and posttest data obtained were assessed using Microsoft Excel and subjected to statistical analysis by McNemar–Bowker test to compare the difference in
correct responses for each question and paired t-test for overall score comparison. All statistical calculations were performed using EPI INFO Version 3.5.3. The statistical significance level was set at \( P < 0.05 \).

**RESULTS**

A total of 50 PGs from different disciplines involved in pre-KAP and post-KAP questionnaire survey. Mean scores were compared pre and post educational intervention. The results implicated that the participants had good theoretical knowledge even before educational intervention but had statistical significance in overall practice and attitude-based questions only after educational intervention as shown in Table 1.

**Knowledge-based questions**

- Question 1 was about their knowledge regarding the term PV. Awareness regarding the term PV was 100% in both pre-KAP and post-KAP questionnaire survey. Question 2 was about the features of PV. According to the data, 84% of participants provided correct responses in pretest and 92% of participants gave correct responses in posttest. However, response rates were not statistically significant after educational interventions (\( P > 0.05 \)). Question 3 was regarding the location of the WHO Collaborating Centre for PV in India. Only 48% of participants were able to give correct responses in the pretest when compared to the posttest, the response rate was 58% (\( P > 0.05 \)). Question 4 sought information regarding the center responsible for setting up the guideline and running a PV center. Response rates for Question 4 differ significantly between pre-KAP and post-KAP, i.e., 46% to 88% (\( P < 0.001 \)). Question 5 was regarding the WHO online database available for reporting of ADRs. In this, 72% of participants gave correct responses in pre-KAP and 88% of participants gave correct responses in post-KAP (\( P < 0.05 \)). Question 6 investigated about the most frequent body system affected by ADR. Response rates for Question 6 from participants were not statistically significant between pre-KAP and post-KAP, i.e., 60% to 68% (\( P > 0.05 \)). Question 7 sought information about the scale used to assess the causality of ADRs. Response rates for Question 7 from participants were statistically significant between pre-KAP and post-KAP, i.e., 32% to 82% (\( P < 0.001 \)). Question 8 was information about the location of the international adverse drug reporting center. The results were statistically significant (\( P < 0.05 \)) between pre-KAP and post-KAP, i.e., 60% to 84%. Question 9 was about their awareness of the PV committee available and functioning in our institute. According to the data for question 9, 66% of participants were given correct responses in pre-KAP and 98% of participants were given correct responses in post-KAP. Response rates were statistically significant (\( P < 0.001 \)). Question 10 was about the steps to be followed once ADR is detected. Response rates for Question 10 from participants were statistically significant between pre-KAP and post-KAP, i.e., 68% to 90% (\( P < 0.05 \)) [Figure 1].

**Attitude-based questions**

- Question 11 investigated about the attitude toward mandatory reporting of ADRs. The percentage of correct responses for pre-KAP and post-KAP was 98% and 100%, respectively. Question 12 was about their thoughts of any legal consequences for the reporter on ADR reporting. Thirty-eight percent participants responded correctly as no in pre-KAP survey which significantly increased to 62% in post-KAP (\( P < 0.05 \)). Question 13 was about the coverage of the topics – ADR monitoring and PV in curriculum. The percentage of correct responses for pre-KAP and post-KAP was 44% and 76%, respectively. The results are statistically significant between pre-KAP and post-KAP (\( P < 0.05 \)). Question 14 was about their attitude toward the educational and orientation programs of having a positive impact on ADR reporting. The results are statistically not significant between pre-KAP and post-KAP (\( P > 0.05 \)). The percentage of correct responses for pre-KAP and post-KAP was 82% and 94%, respectively. Question 15 investigated about the necessity of the identity of the patient and reporter to avoid duplication of the reports. The results are statistically significant between pre-KAP and post-KAP (\( P < 0.05 \)).

**Table 1: Comparison of mean score**

| Question | Preeducational Intervention | Posteducational Intervention | \( P \) |
|----------|----------------------------|-----------------------------|--------|
| Knowledge | 31.70±9.844                | 42.40±6.484                | 0.092  |
| Attitude | 33.60±12.759               | 42.60±7.893                | 0.012* |
| Practice | 32.60±13.722               | 39.80±15.073               | 0.043* |

* \( P < 0.05 \) are significant

**Figure 1:** Comparison of pre- and post-interventional correct responses of knowledge-based questions
responses for pre-KAP and post-KAP was 74% and 94%, respectively [Figure 2].

**Practice-based questions**

Question numbers 16–20 were practice-based questions. Question 16 was whether they had reported an ADR. According to the data for question 16, 24% of participants had given correct responses in pre-KAP and 26% of participants had given correct responses in post-KAP. However, response rates were statistically not significant ($P > 0.05$). Question 17 was about their practice in correctly filling up a suspected adverse drug reporting form. The percentage of correct responses for pre-KAP and post-KAP was 64% and 92%. The results are statistically significant between pre-KAP and post-KAP ($P < 0.05$). Question 18 sought information about any difficulty in filling up their ADR forms. Response rates for Question 18 from participants were statistically significant between pre-KAP and post-KAP, i.e., 58% to 88% ($P < 0.05$). Question 19 was about the methods they would prefer for sending ADR information to an ADR reporting center. Participant response rates of reporting ADRs by different methods were not statistically significant (94% and 96%). Question 20 sought information on the factors that discourage them from reporting an ADR. The results are not statistically significant between pre-KAP and post-KAP ($P > 0.05$). The percentage of responses for pre-KAP and post-KAP was 86% and 96%, respectively [Figure 3].

**DISCUSSION**

PGs are an invaluable source of collecting and reporting the ADRs. The overall response for knowledge-based questions in this study was highly appreciable when compared to attitude- and practice-based questions. Similarly, a study by Kulmi et al. also proved good theoretical knowledge about ADR reporting and PV.\(^{[13]}\)

Increased ADR reporting. In our study, the educational intervention included PowerPoint presentation and also hands-on training in filling up the ADR forms and causality assessment which will overcome the practical issues of the PGs when compared to the study done by Kalikar et al. having lectures alone as an intervention.\(^{[14]}\)

Previous literatures had shown that educational intervention in health-care professionals leads to a significant increase in KAP of PV.\(^{[15]}\) In this study also, after an educational intervention, there was a significant increase in the responses of PGs in knowledge-, attitude-, and practice-based questions. The potential reason behind the similarity in the above studies could be the lack of curriculum in pharmacovigilance both at undergraduate level and PG level. So after an educational intervention, an increase in responses is observed in both the studies. This could be a promising step taken to increase the number of ADRs reported in our institute. Studies had also shown that enhancing the knowledge and attitude of the medical graduates helps in the practice of increasing ADR reporting to the concerned authorities.\(^{[16-18]}\)

In the present study, the PG knowledge about the center responsible for setting up the guideline and running a PV center improved from 48% to 88% after an educational intervention, and the response rate when compared to pretest increased significantly after an educational intervention for the causality assessment methods from 32% to 82%. These findings were again supported by Ramesh and Parthasarathi study.\(^{[19]}\) We could infer from the above studies that assessment methods of causality are not familiar among the PGs. Knowledge regarding the assessment scales for causality, severity, and preventability of ADR is a must among all health-care professionals.

The educational intervention had cleared the attitude of participants that there will be no legal consequences on
reporting an ADR. PV program of India clearly states that the submitted ADR report does not have any legal implication on the reporters. The patients’ identities are held in strict confidence and protected to the fullest extent. Therefore, health-care providers are encouraged to report ADRs for a better understanding of the risk associated with the use of medicines and to safeguard the health of the Indian population.

This study evidenced the lack of PV topic and ADR reporting in their curriculum. Previous literatures also suggest a need for the inclusion of PV and its reporting as a part of their curriculum.[13,20]

Sharma and Kellarai felt that the interns and PGs were poor in ADR reporting, as >65% had not reported any ADR.[21] It is alarming and disheartening to note that, in this study also, the PGs who had reported an ADR previously were very minimal. The respondents’ practical issues on ADR underreporting were not aware of filling up the suspected ADR form due to nonavailability of ADR forms and lack of time. Several studies had demonstrated the same trend of underreporting among health-care professionals.[22-24]

Around 58% of participants preferred to send ADR to the PV cell through the mail, 18% of them directly in person, 10% through post, and around 10% through telephone. The practice pattern preferred in this study was the same as the study done by Upadhyaya et al.[25]

A few limitations of this study were findings could not be applied to the wider community as the study was restricted to PGs of MMCH and RI. Thus, the need for reporting ADRs had to be emphasized to all the PGs by periodical educational interventions on a routine basis. Therefore, we recommend that such educational intervention programs should be a part of Internship/undergraduate training programs. Several similar studies should be conducted among all health-care professionals and paramedics to improve the KAP of PV in India. Future works of educating and creating awareness among the public regarding the spontaneous ADR reporting form available in different languages such as Hindi, Tamil, and Telugu should be done for improving the PV practice in India.

Strengths and limitations

Only a very few studies have been done to assess KAP of PV among the PGs in a tertiary care teaching hospital to the best of our knowledge. Further, comparing the pretest and the posttest values is the definitive proof that a medical intervention can be very much helpful in improving the KAP of PV. The major limitation of our study was essentially the small sample size and it could have been applied to a wider medical community.

CONCLUSION

Educational intervention had proven to be an effective tool in improving the KAP of PV in the present study. Revisions to include the application of PV in medical practice should be the necessary step in the present academic curriculum. Awareness about PV and ADRs should be given priority. This knowledge would help them to detect adverse effects and report to the concerned authorities. Educational intervention on a routine basis for the PGs and other health professionals can increase the number of adverse events reporting in the tertiary care center. The overall increase in the reporting can strengthen the signals. Strengthening of signals is a basic necessity for any regulatory and safety actions by regulatory authorities. Ensuring a better safety profile for drugs can be done only through PV. Further studies are needed to strengthen the effectiveness of PV activities in India.

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Conflicts of interest

There are no conflicts of interest.

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