



IMPACT OF EDUCATIONAL INTERVENTION ON KNOWLEDGE, ATTITUDE AND PRACTICE OF PHARMACOVIGILANCE AMONG MEDICAL GRADUATES OF RURAL TERTIARY CARE, TEACHING HOSPITAL OF CENTRAL INDIA

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ABSTRACT

Objectives: To assess the awareness of Pharmacovigilance among the medical graduates and to evaluate the need of inclusion of KAP (Knowledge, Attitude and Practice) of Pharmacovigilance in Internship Training Programme as an educational intervention. **Material and Methods:** The present study was conducted in the Internship orientation program in a rural hospital of central India. It was a Hospital Based Cross Sectional Study in which 65 Interns (medical graduates) were participated. Semi-structured, Pre-Designed, Pre-tested Questionnaire was used for data collection. Data was entered and analyzed using statistical software 'EPI INFO 3.5.3'. **Results:** In our study a total of 65 medical graduates were responded and involved in the pre KAP and post KAP survey questionnaires. The overall response rate between pre intervention and post intervention was statistically significant and that shows effectiveness of educational intervention for improving awareness of Pharmacovigilance among medical graduates. **Conclusion:** Imparting the knowledge and awareness of Pharmacovigilance among the medical graduates by mean of continuous educational intervention would bring update of knowledge for drug safety into their everyday clinical practice and also bring the adverse drug reactions(ADRs) reporting culture among them.

Keywords: Pharmacovigilance, Medical Graduates, Educational Intervention, Adverse drug reaction.

INTRODUCTION

Pharmacovigilance is a growing discipline for the last 15 years because of rise of adverse drug reactions.¹⁻² Pharmacovigilance program of India was started with the aim of generating the database of adverse drug reactions (ADRs) among Indian population. Pharmacovigilance program was started to identify adverse effects in shortest possible time so that harm can be avoided or minimized.

Effective generation of adverse effects data help in practicing evidence-based medicines and thus prevents many adverse drug reactions. They affect both children and adults with varying magnitudes, causing both morbidity and mortality.³⁻⁶

Medical graduates are in a position to play a major key role in Pharmacovigilance programs,⁷⁻⁸ but under-reporting is very common, with an estimated median under-reporting rate (defined as percentage of ADRs detected from intensive data collection that were not reported to relevant spontaneous reporting systems) of 94%,⁹ and occurs frequently for serious and unlabeled reactions.¹⁰⁻¹¹ This can delay reporting of important ADRs. Studies from different settings indicate inadequate knowledge about Pharmacovigilance among healthcare professionals as well as attitudes that are associated with a high degree of under-reporting.¹²⁻¹⁷ Pharmacovigilance is still in its infancy in India and there exists very limited knowledge about this discipline. However, programme in India lacks continuity due to lack of awareness and inadequate training to medical graduates about drug safety monitoring.¹⁸ Assessment of awareness of pharmacovigilance among the medical graduates for reporting of adverse drug reactions. Therefore this study was conducted to assess awareness of pharmacovigilance among the medical graduates and to evaluate the impact of an educational intervention for improving awareness of Pharmacovigilance among medical graduates undergoing Internship Training Program in an Indian tertiary care teaching hospital.

MATERIAL AND METHODS

Study setting

Study was conducted at Kasturba Hospital, of Mahatma Gandhi Institute of Medical Sciences, Sewagram, a rural tertiary care teaching hospital in Central India where Regional ADR reporting centre exists in the Dept. of Pharmacology, under PVPI (Pharmacovigilance Program of India) since year 2011.

Type of study

It was a prospective Knowledge Attitude Practice (KAP) Questionnaire Study.¹⁹

Sample Size

Convenient Sampling method was used in which 65 medical graduates, undergoing Internship Training Program were enrolled.

Data Collection

Semi-structured, Pre-Designed, Pretested Questionnaire was used for data collection as a research tool. It was modified according to study set up¹⁹. This KAP questionnaire survey was conducted during Internship Orientation Program in March 2012. The final KAP questionnaire was designed by giving equal emphasis on knowledge, attitude and practice of pharmacovigilance. In order to preclude any potential bias, the disclosure of name of the responder was made optional. Pre-KAP questionnaire was administered at the beginning of the study, in order to identify the knowledge of pharmacovigilance. The Pre-KAP survey questionnaire was analyzed question wise and their percentage values were calculated. In case of any unanswered question, a participant was excluded from the study. An interactive educational intervention was designed separately for all participants of Pre-KAP questionnaire survey in order to facilitate the transfer of knowledge of pharmacovigilance program.

Intervention

The educational intervention was conveyed to the participants through presentation on how to report a suspected adverse drug reaction followed by economic and epidemiological importance of reporting ADRs and its effect on patient safety, as well as on the definition of pharmacovigilance, classification of ADRs (i.e. in terms of causality assessment, seriousness and severity, ADR reporting cards from various countries, ADR alert cards, WHO online database for reporting adverse drug reactions). The session was conducted by trained faculty. The practical part of the intervention included practical examples of how to document ADRs using ADR notification and documentation forms. After the educational intervention, all participants of Pre-KAP questionnaire who participated in educational intervention program were given Post-KAP questionnaire which was analyzed and their percentage values were calculated.

Statistical Test

To measure changes in the awareness of Pharmacovigilance among the healthcare professionals between pre-intervention and post intervention and to evaluate the impact of effectiveness of educational intervention among healthcare professionals, the *chi-square test* was used to compare the difference in correct responses for each question. All statistical calculations were performed using EPI INFO Version 3.5.3. The level of statistical significance was set at $p < 0.05$.

RESULTS

A total of 65 medical graduates were responded and involved in the Pre-KAP and post-KAP survey questionnaires. Questionnaire was similar in both pre-KAP and post-KAP sessions having 24 questions.

Question No.1 sought information about definition of Pharmacovigilance. Response rates for Question 1 differ significantly between pre-KAP and post-KAP i.e. after educational interventions was 57% to 97% respectively. (P value < 0.001) [Figure 1]

Question No.2 investigated important purpose of Pharmacovigilance. According to the data for question 2, 29% of participants were given correct response in pre-KAP, 51% participants were given correct response in post-KAP. But response rates were statistically not significant after educational interventions (P value > 0.05). [Figure 1]

Question No.3 sought information about methods commonly employed by the pharmaceutical company for monitoring ADRs of new drugs once they are launched in the market. Response rates for Question 3 differ significantly between pre-KAP and post-KAP i.e. 55% to 77%. (P value < 0.001) [Figure 1]

Question No.4 investigated awareness of reporting serious adverse events with regulatory body in India. In this, 17% of participants were given correct response in pre-KAP, 69% of participants were given correct response in post-KAP (P value < 0.001). [Figure 1]

Question No.5 sought information about international center for adverse drug reactions monitoring. Response rates for Question 5 from participants were statistically significant between pre-KAP and post-KAP. i.e. 25% to 86% (P value < 0.001). [Figure 1]

Question No.6 sought information about agency in United States of America involved in drug safety issues. Response rates for Question 6 from participants were statistically significant between pre-KAP and post-KAP. i.e. 49% to 88%. (P value < 0.001). [Figure 1]

Question No.7 sought information about major risk factors for the occurrence of maximum adverse drug reactions. Response rates for Question 7 from participants were statistically significant between pre-KAP and post-KAP i.e. 75% to 100% (P value < 0.001) [Figure 1]

Question No.8 investigated which regulatory body is responsible for monitoring for ADRs in India. Response rates for Question 8 from participants were statistically significant between pre-KAP and post-KAP i.e. 65% to 91% (P value < 0.001) [Figure 1]

Question No.9 sought information about most commonly used causality assessment of ADRs. According to the data for question 9, 23% of participants were given correct response in pre-KAP, 89% of participants were given correct response in post-KAP. But response rates were statistically not significant (P value > 0.05). [Figure 1]

Question No.10 investigated the ADR reporting system to the respective countries by means of match the following. The results were statistically significant between pre-KAP and post-KAP i.e. 5% to 94% (P value < 0.001). [Figure 1]

Question No.11 sought information about knowledge of regional Pharmacovigilance centre in India. The overall result between pre-

KAP and post-KAP was statistically significant (P value < 0.001) response for pre-KAP and post- KAP (57% and 94%) [Figure 1]

Question No.12 investigated about WHO online data base for reporting ADRs. The results are statistically significant between pre-KAP and post-KAP (P value < 0.001). The percentage of correct response for pre-KAP and post-KAP was 25% and 83% [Figure 1]

Question No. 13 sought information about rare ADRs that can be identified during which phase of a clinical trial. The results are statistically not significant between pre- KAP and post- KAP (P value greater than 0.05). The percentage of correct response was for pre-KAP and post- KAP (32% and 46%) [Figure 1]

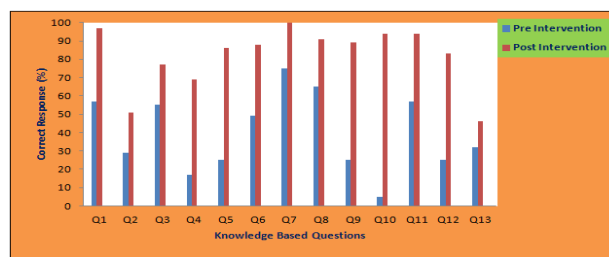


Figure 1: Comparison of Pre & Post-Interventional correct responses of knowledge based Questions

Question No.14 sought information about professional responsibility for reporting ADRs. The percentage of correct response for pre-KAP and post- KAP were 88% and 98% respectively. [Figure 2]

Question No.15 investigated about factors discouraged them for reporting ADRs. The results are statistically significant between pre-KAP and post-KAP (P value < 0.001). The percentage of correct response for pre-KAP and post-KAP were 28% and 95% respectively. [Figure 2]

Question No.16 investigated about attitude of reporting ADRs. The results are statistically significant between pre-KAP and post-KAP groups (P value < 0.001). The percentage of correct response for pre-KAP and post-KAP were 69% and 98% respectively. [Figure 2]

Question No. 17 investigated about opinion about establishing ADR monitoring centre in every hospital. The results are not statistically significant between pre-KAP and post-KAP. The percentage of correct response for pre-KAP and post- KAP were 43% and 88% respectively. [Figure 2]

Question No. 18 to 19 sought information about attitude of Pharmacovigilance by means of 'yes' or 'no' questionnaires. The percentage of correct response between pre-KAP and post-KAP was statistically significant. (P value < 0.001). [Figure 2]

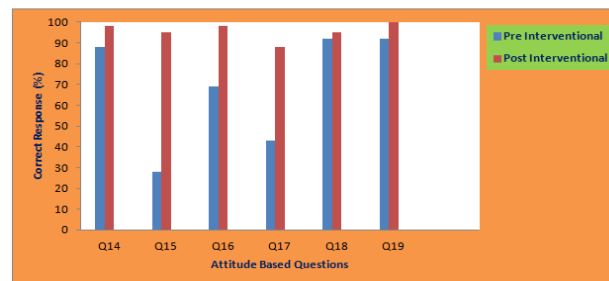


Figure 2: Comparison of Pre & Post-Interventional correct responses of Attitude based Questions

The aim of the Question No.20 was to assess health care professionals' perception and practice on prevention of adverse drug reaction. The percentage of correct response for pre-KAP and post-KAP were 54% and 100% respectively (P value < 0.001) [Figure 3]

Finally, Questions No. 21 to 24 sought information about practice of Pharmacovigilance by means of 'yes' or 'no' questionnaires. In all practice based questions, the correct response was significantly improved in post interventional session. (P value <0.001) i.e. 63% to 100% for question 21, 29% to 100% for question 22, 26% to 100% for question 23 and from 92% to 100% for question 24. [Figure 3]

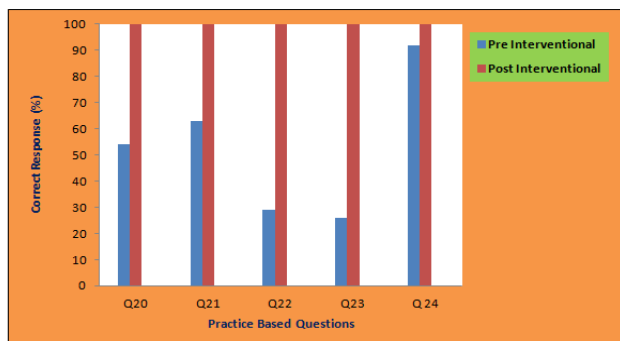


Figure 3: Comparison of Pre & Post-Interventional correct responses of Practice based Questions

DISCUSSION

This study was conducted among fresh batches of Interns to assess their knowledge and attitude about pharmacovigilance as they are the connecting bridge between physicians and patients. During internship orientation program, an educational intervention on pharmacovigilance was arranged; where hospital based ADR reporting and monitoring system exist. The present study shows that, there is improvement in responses for knowledge based questions as compared to attitude and practice. The overall results of the post-KAP questionnaire in our study was encouraging and revealed that medical graduates enhanced awareness helped in increase in the number of ADR reports submitted to Department of Pharmacology. Studies has also shown that enhancing the knowledge and attitude of the medical graduates helps in the practice of increasing ADR reports to the concerned authorities.²⁰⁻²² This finding of our study indicates that educational interventions improves awareness of pharmacovigilance among medical graduates and helps them in their clinical practice. Based on our study results and the finding of Cosentino *et al*²³ and Figueras *et al*²⁴ recommend including "Pharmacovigilance" as a topic in continuing education programs should be held regularly. It was also evident from our study that educational intervention helps medical graduates to know our national centers for pharmacovigilance as well as international centers for reporting. In our study, it also helps the intern to know about regulatory bodies involved in the programme and also the causality assessment of adverse drug effects. This was demonstrated by an increase in the correct responses in pre and post KAP question no.8 and 9 [Figure 1].

We observed in our study that medical graduates lacks the knowledge regarding existing adverse drug reactions reporting system in across various countries. This was supported by a study conducted by Madhan Ramesh *et al*.²⁵ which stated that doctors were less aware of the national and international Pharmacovigilance programs. In the literature, a lack of time and knowledge about ADRs is often considered to be a cause of under reporting²⁶⁻²⁸. This was also supported by the study conducted by Chatterjee *et al*²⁹ which stated that a main reason for under reporting of ADRs being the clinical negligibility of the adverse reaction due to lack of time and little knowledge about the types of reactions to be preferentially reported.

Important limitations of this study are that, findings could not be applied to the wider community as the study was restricted to medical graduates doing internship at Kasturba Hospital, Sewagram and similar subsequent interventions are required so as to confirm the above findings. Therefore we recommend that such educational intervention programs should be included in the Internship training programs. Several similar studies should be

conducted among health care professionals to improve the knowledge, attitude and practice of pharmacovigilance in India.

CONCLUSION

In conclusion, the results of the present study demonstrate that an educational intervention can increase awareness about Pharmacovigilance among the medical graduates and this knowledge would help them in clinical practice to detect adverse effects and report to the concerned authorities. Further studies are needed to strengthen effectiveness of pharmacovigilance activities in India.

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