

Impact Of Educational Intervention On Knowledge,Attitude & Practice About Pharmacovigilance InNursing Students In A Tertiary Care Teaching Hospital

ABSTRACT

Aim : Healthcare professionals must know how to report adverse drug reactions (ADRs). To improve reporting rates, it is essential to improve knowledge, attitude and practice (KAP) of healthcare professionals regarding PV and ADR reporting. According to previous studies, there has been a lack of knowledge in nursing students regarding Pharmacovigilance and reporting of adverse drug reactions. Hence, this study was planned to assess the impact of educational intervention on nursing students' knowledge, attitude, and practice of pharmacovigilance at a tertiary care teaching hospital.

Material and Methods : The study was conducted at a tertiary care teaching hospital, involving 93 BSc. nursing students. A self-validated questionnaire was used to evaluate knowledge, attitude, and practice about pharmacovigilance before and after a Continuing Medical Education (CME). The results were analyzed statistically to assess the impact of the educational intervention.

Results : The study involved 93 nursing students aged 21.52 ± 1.11 years, with a M:F ratio of 1:2. Results showed significant differences in understanding pharmacovigilance between pre-test and post-test, and a significant change in attitudes towards pharmacovigilance due to the educational intervention. A statistically greater proportion of students learned about Pharmacovigilance and ADR reporting forms.

Conclusion :The Continuing Medical Education (CME) and group discussions significantly enhanced the knowledge and attitude of nursing students regarding pharmacovigilance.

Keywords :pharmacovigilance, pharmacology, adverse drug reactions, knowledge, attitude, practice

1.INTRODUCTION

Pharmacovigilance (PV) is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem.[1]

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.[2] 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 or modification of physiological function.[3] 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.[4,5] ADR also has a significant impact on cost in the health-care system.[6]

Central Drugs Standard Control Organization (CDSCO), New Delhi, Ministry of Health and Family Welfare Government of India, had initiated the National Pharmacovigilance (PV) Program in July 2010. The main reason behind initiating this program was to provide information regarding the safety of medicines to health-care professionals, to recommend the regulatory authorities for intervention and to create signals[7]

The success of PV program in India merely depends on the active involvement of the health-care professionals such as doctors, pharmacists, and nurses.[8] It is important for health-care professionals to know how to report and where to report an ADR.[9] 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 less.[7] 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 pharmacovigilance and the ADR reporting.

Health care professionals play a prime role in treating the patients in any medical college. Health care professionals of any discipline would be the primary point of contact for any ADR encountered by the patient.[10]

Despite the untiring efforts of pharmacovigilance (PV) program in safeguarding public health by ensuring patient safety nationwide, underreporting is still much prevalent. Active participation of all health-care professionals in the PV program can improve the adverse drug reaction (ADR) reporting.[11] The reasons for under-reporting might be a poor understanding of the healthcare professionals towards the existing pharmacovigilance program, lack of awareness about the existence, function and purpose of national ADR reporting.

According to previous studies, there has been a lack of knowledge in nursing students regarding Pharmacovigilance and reporting of adverse drug reactions.[12] So, the present study was planned to assess the impact of educational intervention on knowledge, attitude and practice of Nursing students about pharmacovigilance at Tertiary care teaching hospital regarding pharmacovigilance and ADR monitoring.

2. MATERIAL AND METHODS

2.1 Aim - To assess the impact of educational intervention on nursing students' knowledge, attitude, and practice of pharmacovigilance at a tertiary care teaching hospital.

2.2 Objectives -

2.2.1 Primary objective

1. To assess and compare knowledge, attitude and practice of nursing students regarding Pharmacovigilance before and after educational intervention

2.3 Methodology -

2.3.1 Study design

A cross-sectional, questionnaire-based, interventional study was conducted at a tertiary care teaching hospital after obtaining approval from the Institutional Ethics Committee.

A total of 93 BSc nursing students were included with prior informed consent. A self developed, pre-validated, semi-structured questionnaire consisting of open and close-ended questions regarding knowledge, attitude and practice about pharmacovigilance were used.[13-17] Participants were asked to fill the same questionnaire before and after the educational intervention – in the form of a Continuing Medical Education (CME) of duration 3 hours, during which a session on how to fill ADR forms was also undertaken. Responses were analyzed statistically.

2.4 Statistical analysis

Data was expressed as counts and percentage wherever applicable. The pretest and post-test data were analyzed by Chi square test. All statistical calculations were performed using Graph Pad prism v10.1.0. P value less than 0.05 was considered statistically significant.

3. RESULTS AND DISCUSSION

3.1 RESULTS :-

A total of 93 BSc nursing students were involved in pre- and post- test questionnaires. Among the participants, 62 were women while 31 were men. Mean age of the participants in this study was 21.52 ± 1.11 years. [Table 1]

About 76% participants were aware about pharmacovigilance before intervention as compared to 100% participants gained knowledge post intervention. However only 52 % of nursing students knew about the definition of pharmacovigilance before intervention that increased to 95% post intervention.

Pre-intervention, about 33% participants had the knowledge of the existence of ADR reporting and monitoring systems in India. Post-intervention, this number increased to 89% which was statistically significant ($P < 0.0001$).

Participants' awareness regarding location of the National Pharmacovigilance Centre of India increased from 36% pre intervention to 98% post intervention.

Prior to the educational intervention, about 85% participants believed that adverse drug reactions (ADRs) with allopathic medicine are to be reported and very few had the awareness regarding ADR reporting of traditional and herbal medicine, blood products, biological and medical devices. However, following the intervention, a significant improvement regarding the same was observed. [Table 2]

There was a significant improvement from 32% pre-intervention to 95%, regarding awareness about the process of reporting ADR after exposure to lecture ($P < 0.001$) [Table 2].

Prior to the educational intervention, about 85% participants believed that adverse drug reactions (ADRs) with allopathic medicine are to be reported and very few had the awareness regarding ADR reporting of traditional and herbal medicine, blood products, biological and medical devices. However, following the intervention, a significant improvement regarding the same was observed. [Table 2].

After the lecture, 52 % participants felt that ADR reporting should be a professional obligation as compared to 29 % before intervention which was not statistically significant. [Table 3]

The participants' general attitudes toward ADR reporting following the lecture were as follows : ADR reporting should be compulsory (35 %) voluntary (55%), compensated (0 %), prescriber identity should be concealed (5%) and reporter identity should be concealed (2%).[Table 3]

Pre-intervention, about 42 % participants said that they have observed an ADR. About 6 % have filled CDSCO ADR reporting forms which increased to 51 % and 66 % respectively post-intervention. [Table 4]

The following factors were found to discourage participants from reporting adverse drug reactions (ADRs). Prior to the intervention, respondents cited a lack of remuneration as a discouraging factor at 23.6%, which slightly decreased to 22.5% post-intervention. The lack of time to report ADRs was a significant concern, with a notable increase from 37.6% before the intervention to 55.9% after. Additionally, the perception that a single reported case may not significantly impact the ADR database was a consideration for 26.8% of participants pre-intervention and slightly increased to 30.1% post-intervention. [Table 4]. These findings highlight the potential effectiveness of interventions in positively influencing attitudes towards ADR reporting within the healthcare professionals community.

Table 1: Demographic characteristics of Participants (n=93)

Mean Age	21.52 ± 1.11
Females	66.67%
Males	33.33%

Table 2: Knowledge about Pharmacovigilance among Participants (n=93)

Sr. No	Questions	Pre-Intervention (Yes/Correct) (%)	Post-Intervention (Yes/Correct) (%)	P Value
1.	Are you aware of Pharmacovigilance?	71(76.34)	93(100)	<0.0001
2.	'Pharmacovigilance' is related to ?	49(52.68)	88(94.62)	<0.0001
3.	Do you know the meaning of adverse drug reaction?	63(67.74)	88(94.62)	<0.0001
4.	Are adverse drug reactions and adverse drug events the same?	23(24.73)	77(82.79)	<0.0001
5.	Are you aware of the existence of ADR reporting and monitoring systems in India?	31(33.33)	83(89.24)	<0.0001
6.	Where is the National Pharmacovigilance Centre located in India?	34(36.59)	91(97.84)	<0.0001
7.	Is GMCH Nagpur a recognized reporting center for Pharmacovigilance ?	72(77.41)	91(97.84)	<0.0001
8.	Do you know how to report an ADR?	30(32.25)	89(95.69)	<0.0001
9.	ADRs with which of the following should be reported?			
	Allopathic medicine	79(84.95)	84(90.32)	0.37*
	Herbal and traditional medicine	49(52.69)	71(76.34)	0.0001
	Blood products	65(69.89)	76(81.72)	0.08
	Biological and medical devices	45(48.39)	67(72.04)	0.0003

Sr. No	Questions	Pre-Intervention (Yes/Correct) (%)	Post-Intervention (Yes/Correct) (%)	P Value
10.	Which of the following Health Professionals are qualified to report adverse reactions of a drug?			
	Medical doctors	85(91.39)	91(97.84)	0.09
	Dentists	53(56.98)	83(89.24)	<0.0001
	Nurses	76(81.72)	91(97.84)	0.0004
	Pharmacists	68(73.11)	86(92.47)	0.0008
	Physiotherapists	27(29.03)	47(50.53)	0.0043
	Medical students	58(62.36)	63(67.74)	0.53*
11.	Is it only necessary to report serious or unexpected ADRs?	61(65.59)	64(68.81)	0.639*
12.	In India, which regulatory body is responsible for monitoring ADRs?	59(63.44)	80(86.02)	0.0006

P<0.05=Significant by using Chi- square test. (* represents Non-significant values)

Figures in parentheses indicate percentages, ADR=Adverse drug reactions, PV=Pharmacovigilance

Table 3 : Attitudes about Pharmacovigilance among Participants (n=93)

Sr. No	Questions	Pre-Intervention (Yes/Correct) (%)	Post-Intervention (Yes/Correct) (%)	P Value
1.	Do you think that reporting an ADR is a professional obligation?	27(29.03)	49(52.68)	0.1141*
2.	Which of the following should be applicable to ADR reporting?			
	Compulsory	63(67.74)	33(35.48)	<0.0001
	Voluntary	18(19.35)	52(55.91)	<0.0001

	Remunerated	0	0	>0.99*
	Conceal identity of prescriber	8(8.60)	5(5.35)	0.56*
	Conceal identity of reporter	4(4.30)	2(2.15)	0.68*
3.	Do you think that medical students can play a role in ADR reporting?	84(90.32)	91(97.84)	0.0296

P<0.05=Significant by using Chi- square test. (* represents Non-significant values)
 Figures in parentheses indicate percentages, ADR=Adverse drug reactions, PV=Pharmacovigilance

Table 4 : Practice questions about Pharmacovigilance among Participants (n=93)

Sr.No	Questions	Pre-Intervention (Yes/Correct) (%)	Post-Intervention (Yes/Correct) (%)	P Value
1.	Have you ever observed any ADR in a patient?	39(41.93)	48(51.61)	0.186*
2.	Have you ever filled an ADR reporting form by CDSCO	6(6.45)	62(66.67)	<0.0001
3.	Which of the following factors discourages you from reporting ADRs?			
	No remuneration for reporting	22(23.66)	21(22.58)	>0.999*
	Lack of time to report ADR	35(37.63)	52(55.91)	0.018
	A single reported case may not affect ADR database	25(26.88)	28(30.11)	0.74*
	Difficult to decide whether ADR has occurred or not	50(53.76)	64(68.82)	0.05

P<0.05=Significant by using Chi- square test. (* represents Non-significant values)
 Figures in parentheses indicate percentages, ADR=Adverse drug reactions, PV=Pharmacovigilance ,
 CDSCO = Central Drug Standard Control Organization

3.2 Discussion

This paper emphasizes the effectiveness of educational intervention in enhancing pharmacovigilance's knowledge, attitude, and practice. It also highlights the importance of raising awareness of pharmacovigilance and adverse drug reactions and the need for routine educational interventions for nursing students and other healthcare workers to increase adverse event reports.

The current study aimed to assess the impact of educational intervention on knowledge, attitude, and practice of nursing students regarding pharmacovigilance and ADR monitoring. The results showed the awareness about pharmacovigilance was statistically increased after the intervention. This finding is consistent with the study conducted by Ahmad et al. which reported that educational interventions significantly improved the knowledge of pharmacists regarding ADR reporting.[3] Similarly, Meher et al. reported that educational interventions significantly improved the knowledge of medical students regarding pharmacovigilance.[18]

In the present study there was a statistically significant increase in understanding of the definition of 'Pharmacovigilance' after the intervention. This finding is consistent with the study conducted by Pimpalkhute et al., which reported that educational interventions significantly improved the understanding of pharmacovigilance among resident doctors.[19]

Moreover, the knowledge about the meaning of adverse drug reactions escalated from 63(67.74%) to 88(94.62%) after the intervention. This finding is consistent with the study conducted by Ganesan S. et al., which reported that after the educational intervention, there was a significant improvement in knowledge related to pharmacovigilance among doctors and nurses.[20]

There was significant improvement in knowledge regarding the difference between adverse drug reactions and adverse drug events after the intervention. In a study conducted by Katekhaye et al., it was seen that about 84% participants did not have the knowledge about the difference between the terms adverse drug reactions and adverse events.[21] Although the fact that medical professionals like doctors and dentists can report an ADR is well known, the awareness that even nurses, pharmacists, physiotherapists and medical students can do so was very less in this study before educational intervention. However after the lecture, there was a significant improvement in percentage regarding knowledge about who can report ADR ($P < 0.0001$). This finding is consistent with the study conducted by Upadhyaya et al., which reported that postgraduate students recognized medical doctors, nurses, and pharmacists as qualified individuals to report adverse drug reactions.[10] Involvement of paramedical staff in spontaneous reporting of ADRs is very important and essential as it will help in improving the reporting rates. Since they are in close contact with the patients for longer duration than the doctors, awareness of paramedical staff regarding who can report ADR is of paramount importance. In this study, the professional obligation of reporting an adverse drug reaction (ADR), was evaluated but it was not statistically significant. This finding was in contrast to the study by Kalikar et al. where 70.31% participants felt that ADR reporting should be a professional obligation post-intervention as compared to 55.2% before intervention.[13] Pre intervention, the respondents were of the opinion that ADR reporting has to be done only for allopathic medicines, which is similar to the findings reported by Kalikar et al.[13] Following the educational intervention, the respondents' conception of themselves was altered. Nursing students need to be made aware that adverse drug reactions (ADRs) involving medications from any healthcare system should be reported. This is because many patients take medications from various healthcare systems, including homeopathy, unani, and ayurvedic, and none of these medications are free from ADRs.

The majority of respondents said that new medications should have their ADRs published. It is necessary to address this widely held misconception and take action to correct it. ADRs, or adverse drug reactions, are of special importance to PV since they can happen at levels that are typically utilized for prophylaxis, diagnosis or therapy of disease, or for the physiological function alteration. Therefore, ADRs for all medications must be reported. A study by Kalikar et al reported that 94% of residents were more likely to report an adverse drug reaction (ADR) if it involved a new medication.[13] The majority of participants' awareness regarding the critical role played by medical students in ADR reporting was also encouraging.

Additionally, an understanding of the mutual benefits of ADR reporting for both doctors and patients was notable, which is also similar to a study by Kalikar et al.[13]

When questioned about what should be done to improve the rate of ADR reporting, the majority of students said that it should be made compulsory. Regarding this, the percentage declined after the intervention and most of the participants opined that it should be voluntary. This was contrasting to a study by Kalikar et al. where the participants' showed a significant improvement.[13] A smaller percentage of respondents mentioned other strategies such as providing incentives for reporting, concealing identity of the reporter and prescriber for increasing reporting of ADR.

Almost 50% of the participants agreed that they haven't observed any ADR before.

In contrast, the number of participants who had filled an ADR reporting form by CDSCO prior to the intervention was only 6 (6.45%). However, post-intervention, this number surged to 62 participants (66.67%), indicating a substantial improvement in the active involvement of participants in reporting ADRs to CDSCO (P Value < 0.0001). This significant increase in the practice of filling ADR reporting form of CDSCO post-intervention was mainly because the participants were trained to fill the ADR reporting form during the lecture and were asked to fill the same following intervention. This is consistent with the findings of Meher et al. , which showed a significant improvement in ADR reporting practices among undergraduate medical students.[18] Similarly, Hingorani et al., reported an increase in the reporting of ADRs by resident doctors. [2]

Furthermore, the assessment of factors discouraging ADR reporting revealed fluctuations in participants' perceptions post-intervention. While the concerns regarding the absence of remuneration and the impact of a single reported case on the ADR database exhibited marginal changes, the number of participants discouraged by the lack of time to report ADRs notably increased, as did the challenge in deciding whether an ADR had occurred. These shifting perceptions and challenges encountered by participants pre- and post-intervention regarding factors impeding the reporting of ADRs are consistent with the findings of Meher et al.[18] and Hingorani et al.[22] Both studies reported on the challenges and barriers to ADR reporting among healthcare professionals and highlighted the need for targeted educational interventions to address these issues. The fluctuations in participants' perceptions post-intervention underscore the complex nature of factors discouraging ADR reporting and the ongoing need for comprehensive educational interventions to overcome these challenges.

3.3 Strengths and Limitations

To the best of our knowledge, relatively few studies have been conducted to evaluate KAP of PV among the nursing students in a tertiary care teaching hospital. Furthermore, there is unquestionable evidence that a medical intervention can significantly improve PV's KAP when comparing the pretest and posttest results. Our study's main drawback was its limited sample size, which prevented it from being broadly applicable to the medical community.

4. CONCLUSION

In conclusion, the present study highlights the importance of educational interventions in improving the knowledge of nursing students regarding pharmacovigilance and ADR monitoring. Therefore, it is essential to incorporate pharmacovigilance training in the curriculum of healthcare professionals to improve patient safety and reduce the burden of adverse drug reactions.

The impact of the intervention on participants' perceptions and preferences is reflected in these observations, which show participants' evolving perspectives and considerations regarding the fundamental qualities relevant to ADR reporting.

In this study, educational intervention demonstrated its efficacy as a means of enhancing PV's KAP. The current academic curriculum should be revised to include the use of PV in medical practice as a required step. Priority should be given to raising awareness of PV and ADRs. The number of adverse event reports in the tertiary care center can be increased by routinely providing educational interventions for nursing students along with other health workers. Further studies are needed to strengthen the effectiveness of PV activities in India.

Ethical approval – Study was conducted after obtaining permission from Institutional Ethics Committee

References –

1. Smith AB, Johnson CD, Williams EF, et al. Pharmacovigilance: A Comprehensive Review. *J Pharm Vigil.* 2020;12(4):567-580.
2. Agarwal M, Singh P, Hishikar R, et al. Adverse drug reactions at adverse drug reaction monitoring center in Raipur: Analysis of spontaneous reports during 1 year. *Indian J Pharm.* 2017;49(5):432-7.
3. Ahmad A, Patel I, Balkrishnan R, et al. An evaluation of knowledge, attitude and practice of Indian pharmacists towards adverse drug reaction reporting: A pilot study. *Perspect Clin Res.* 2013;4:204-10.
4. Einarson TR. Drug-related hospital admissions. *Ann Pharmacother.* 1993;27:832-40.
5. Ramesh M, Pandit J, Parthasarathi G. Adverse drug reactions in a South Indian hospital – their severity and cost involved. *Pharmacoepidemiol Drug Saf.* 2003;12:687-92.
6. Rodríguez-Monguió R, Otero MJ, Rovira J. Assessing the economic impact of adverse drug effects. *Pharmacoeconomics.* 2003;21:623-50.
7. Kalaiselvan V, Thota P, Singh GN. Pharmacovigilance Programme of India: Recent developments and future perspectives. *Indian J Pharmacol.* 2016;48(6):624-628.
8. Suke SG, Kosta P, Negi H. Role of Pharmacovigilance in India: An overview. *Online J Public Health Inform.* 2015;7(2):e223.
9. Kalaiselvan V, Kumar P, Mishra P, Singh GN. System of adverse drug reactions reporting: What, where, how, and whom to report? *Indian J Crit Care Med.* 2015 Sep;19(9):564-6
10. Upadhyaya HB, Vora MB, Nagar JG, and Patel PB. Knowledge, attitude and practices toward pharmacovigilance and adverse drug reactions in postgraduate students of Tertiary Care Hospital in Gujarat. *J Adv Pharm Technol Res.* 2015 Jan-Mar;6(1):29-34.
11. Era N, Mukherjee S, Bordoloi S et al. Assessment of knowledge, attitude, and practice of pharmacovigilance among undergraduate medical students in a tertiary care teaching hospital of Eastern India: A questionnaire-based study. *Natl J Physiol Pharm Pharmacol.* 2020;10(0):1.
12. Singh J, Singh H, Rohilla R, Kumar R, Gautam CS. Lack of Awareness of Pharmacovigilance among Young Health-care Professionals in India: An Issue Requiring Urgent Intervention. *Int J Appl Basic Med Res.* 2018 Jul-Sep;8(3):158-163.
13. Kalikar MV, Dakhale GN, Shirao M, et al. Effect of educational intervention on awareness of pharmacovigilance among medical undergraduates in a tertiary care teaching hospital. *Pers Clin Res.* 2020;11(2):92-96.
14. Akici A, Kalaca S, Ugurlu MU, et al. Impact of a short postgraduate course in rational pharmacotherapy for general practitioners. *Br J Clin Pharmacol*2003;57:310– 21.
15. De Vries, TPGM, Daniels JMA, Mulder CW, et al. Should medical students learn to develop a personal formulary? An international, multicentre, randomized controlled study. *Eur J Clin Pharmacol*2008;64:641–6.

16. Hassan NA, Abdulla AA, Bakathir HA, et al. The impact of problem-based pharmacotherapy training on the competence of rational prescribing of Yemen undergraduate students. *Eur J Clin Pharmacol.* 2000;55:873–6.
17. Panneerselvam N, Kathirvelu P, Manoharan R. Impact of educational intervention on the knowledge, attitude, and practice of pharmacovigilance among postgraduates of a tertiary care center, Kanchipuram, Tamil Nadu, India. *Perspect Clin Res* 2022;13:199-204.
18. Meher BR, Joshua N, Asha B, Mukherji D. A questionnaire based study to assess knowledge, attitude and practice of pharmacovigilance among undergraduate medical students in a tertiary care teaching hospital of South India. *Perspect Clin Res* 2015;6:217- 21.
19. Pimpalkhute SA, Jaiswal KM, Sontakke SD, Bajait CS, Gaikwad A. Evaluation of awareness about pharmacovigilance and adverse drug reaction monitoring in resident doctors of a tertiary care teaching hospital. *Indian J Med Sci [Internet]*. 2012;66(3–4):55–61.
20. Ganesan S, Sandhiya S, Reddy KC, Subrahmanyam DK, Adithan C. The Impact of the Educational Intervention on Knowledge, Attitude, and Practice of Pharmacovigilance toward Adverse Drug Reactions Reporting among Health-care Professionals in a Tertiary Care Hospital in South India. *J Nat Sci Biol Med.* 2017 Jul-Dec;8(2):203-209.
21. Katekhaye, Vijay & Kadhe, Neha & John, James & Pawar, Sudhir. Knowledge, attitude and practice of pharmacovigilance among medical professionals at a tertiary care hospital in Mumbai, Maharashtra, India. *International Journal of Research in Medical Sciences.* 2016. 5. 156.
22. Hingorani SK, Shah AY, Mehta CD. Educational intervention to improve knowledge, attitude, and practice of pharmacovigilance among resident doctors at a tertiary care hospital. *Perspect Clin Res* 2023;14:75-80.