Impact Of Educational Intervention On Knowledge, Attitude & Practice About Pharmacovigilance In Nursing Students In A Tertiary Care Teaching Hospital In India: A Cross-Sectional Study

ABSTRACT

Background: It is crucial for healthcare professionals to 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 Pharmacovigilance (PV) and adverse drug reactions (ADR) reporting. According to previous studies, there has been a lack of knowledge in nursing students regarding Pharmacovigilance (PV) and reporting of adverse drug reactions (ADR). 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 in India.

Material and Methods : This was an interventional study conducted among 93 BSc nursing students at a tertiary care teaching hospital, India. Each participant was explained the purpose of study and asked to fill in a questionnaire about their knowledge, attitude and practice of pharmacovigilance. The post-KAP questionnaire was re-circulated among participants at the end of the intervention and data was analyzedusing Chi square test.

Results : The study involved 93 BSc nursing students aged 21.52 ± 1.11 years, with a male to female ratio of 1:2. All statistical calculations were performed using Graph Pad prism v10.1.0. Results showed significant differences in understanding pharmacovigilance between pre-intervention and post-intervention, 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 aimed at assessing the impact of educational intervention on knowledge, attitude and practice of nursing students about pharmacovigilance at a tertiary care teaching hospital in India 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 and setting :

It was a cross-sectional, questionnaire-based, interventional study which was conducted at a tertiary care teaching hospital in India after obtaining approval from the Institutional Ethics Committee (IEC), Department of Pharmacology, Government Medical College, Nagpur with reference number: 4103EC/Pharmac/GMC/NGP/.

2.3.2 Sample size :

A sample size of 93 BSc nursing students was taken as an arbitrary value i.e the participants who attended the lecture that day, were included with prior informed written consent.

2.3.3 Data collection tool :

The questionnaire was validated by circulating it to a panel of 10 experts in the field of Pharmacovigilance (PV) and suggested modifications were done. It was a self developed, validated, semi-structured questionnaire consisting of open and close-ended questions regarding knowledge, attitude and practice about pharmacovigilance was adapted.[13-17]

2.3.3 Study procedure :

The questionnaire was structured to obtain the demographics of the participants and total 18 questions – 12 about knowledge, 3 about attitude and 3 about practice of reporting ADR they come across during their practice, designed specifically to answer the awareness about pharmacovigilance. Before commencement of the intervention, the objectives of the study and the contents of the questionnaire were explained to each participant. They were assured that the data which was collected would be used only for research purposes and findings will not be revealed by name to anybody. Each participant was given 20 minutes to fill in the questionnaire in the presence of the investigator. The Pre-KAP survey questionnaire was analyzed question wise and their percentage value was calculated. These results depicted an urgent need to sensitize the participants who share the major responsibility in this pharmacovigilance system. Hence, an educational intervention in the form of a Continuing Medical Education (CME) lecture by multiple experts having work experience in the field of pharmacovigilance was planned for all participants. All the participants were encouraged to attend the lecture session. Efforts were made by the investigator in inviting each and every participant by highlighting the importance of their attendance in the lecture. Head of the departments were informed to encourage doctors of their respective department to attend the session.

2.3.4 Educational intervention :

The lecture lasted for 3 hours and consisted of the definition of pharmacovigilance, classification of ADRs (i.e. in terms of types of ADRs, causality assessment, seriousness and severity, Pharmacovigilance, brief about Pharmacovigilance Programme of India (PvPi), hands-on experience in ADR reporting forms) and its effect on patient safety. During the lecture it was emphasized that only 5 minutes are required to complete the ADR reporting form. The post-KAP questionnaire was re-circulated among participants at the end of the intervention and data was analyzed.

2.4 Statistical analysis

Data was expressed as counts and percentage (%) wherever applicable. The pre-intervention and post-intervention 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-intervention and post- intervention questionnaires. Among the participants, 62 were females while 31 were males. The mean age and standard deviation 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%

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?**			

Sr. No	Questions	Pre-Intervention (Yes/Correct) (%)	Post-Intervention (Yes/Correct) (%)	P Value
	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
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 study 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] "Similarly, studies conducted in developing countries, it was observed that the knowledge regarding pharmacovigilance increased after educational interventions" (Rabia Hussain et al. 2019 ; Jha et al. 2014; Varallo et al. 2017).[20-22]

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.[23]

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.[24] "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. Adverse drug reactions(ADRs) 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. [25]

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-intervention and post-intervention regarding factors impeding the reporting of ADRs are consistent with the findings of Meher et al.[18] and Hingorani et al.[25] 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. Similarly educational interventions conducted in workshops or telephone interviews significantly increased the number and relevance of spontaneous ADR reports by pharmacists of developed countries such as Northern Portugal.[26] 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 pre-intervention and post-intervention 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 isrecommended to incorporate pharmacovigilance training in the curriculum of healthcare professionals to improve patient safety and reduce the burden of adverse drug reactions.Increasing awareness about pharmacovigilance will be helpful in improving the status of ADR reporting. 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 Pharmacovigilance's KAP. The current academic curriculum should be revised to include the use of PV in medical practice as a required step.Other measures such as making ADR reporting guidelines available in the form of booklets and displaying posters can also play a useful role.

Priority should be given to raising awareness of Pharmacovigilance (PV) and Adverse Drug Reactions(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 the Institutional Ethics Committee,Department of Pharmacology, Government Medical College, Nagpur.

Reference number: 4103EC/Pharmac/GMC/NGP/).

Consent

As per international standards or university standards, Participants' written consent has been collected and preserved by the author(s).

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