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Original Research Article

Assessment of effect of educational intervention on awareness, attitude, and practice regarding pharmacovigilance practices among patients admitted in a tertiary healthcare center in South India

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ABSTRACT

Background: Adverse drug reactions (ADRs) remain a significant contributor to global morbidity and mortality. Despite the launch of the Pharmacovigilance Programme of India (PvPI) to improve ADR reporting, under-reporting persists largely due to limited public awareness. Active consumer participation is essential for the success of pharmacovigilance systems. Objective of the study was to assess the impact of an educational intervention on the knowledge, attitude, and practice (KAP) regarding pharmacovigilance among inpatients at a rural tertiary healthcare center in South India.
Methods: A prospective crossover study was conducted using a pre-validated KAP questionnaire. Adult inpatients aged 18–75 years, excluding healthcare workers, were enrolled via convenient sampling. An educational session tailored for non-medical individuals was delivered, followed by re-administration of the same KAP tool to assess changes. The target sample size was 175, with an additional 5 participants enrolled within the study period. Ethical approval and informed consent were obtained.
Results: The study included 180 participants (96 males, 84 females) with a mean age of 40.15±15.30 years. Post-intervention, awareness of what constitutes an ADR rose markedly from 27.8% to 97.8%, and belief in the universal possibility of side effects increased from 20% to 98.9%. Willingness to report ADRs in the future improved slightly from 95% to 96.1%, although actual reporting practice remained limited. Overall, the educational session significantly enhanced participant awareness, attitudes, and understanding related to pharmacovigilance.
Conclusions: Structured educational interventions can substantially improve public engagement in pharmacovigilance. Strengthening patient awareness and involvement, particularly in rural settings, is vital to advancing drug safety monitoring in India.

Keywords: Pharmacovigilance, Adverse drug reactions, Patient education, Knowledge, attitude, and practice

INTRODUCTION

Adverse drug reactions (ADRs) are a major cause of morbidity and mortality across all age groups globally. The World Health Organization defines an ADR as "a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease or for the modification of physiological functions".[1] To address this, the Pharmacovigilance Programme of India (PvPI) was launched in 2010 to improve ADR reporting. However, under-reporting remains a major challenge, with India

contributing less than 1% to global ADR data, mainly through healthcare professionals.[2,3]

Pharmacovigilance involves the detection, assessment, understanding, and prevention of adverse effects or any other drug-related issues.[4] Despite India's large pharmaceutical footprint, public awareness and participation remain low.[5] A study from Punjab reported that most ADRs were from anticancer agents, seen predominantly in females (59.75%) and individuals aged 41–60 years (68.29%).[6] In Lithuania, 16.4% of the population lacked awareness of the reporting method, while 55.5% showed a positive attitude.[7] An interventional study in Nepal showed improved knowledge and attitude among rural pharmacists after education.[8]

In Warsaw, 75% of surveyed patients felt consumers share equal responsibility in ADR reporting, while in Portugal, 44.1% were unaware that consumers could report ADRs.[9,10] A Malaysian study found 86% of participants unaware of the reporting system, citing limited understanding and time as barriers.[11] In Surat, after educational sessions, 97% of resident doctors could report ADRs, though initially only 36% reported despite encountering them.[12]

These findings suggest that educational interventions can significantly enhance awareness, attitude, and practice towards ADR reporting. This study aims to assess the impact of such an intervention among inpatients in a tertiary healthcare center in South India, encouraging active public involvement in pharmacovigilance.

METHODS

Study design and ethical approval

A prospective crossover study was conducted using a structured knowledge, attitude, and practice (KAP) survey to assess the impact of an educational intervention on pharmacovigilance awareness among inpatients. The study was approved by the Institutional Scientific Committee (ISC) and Institutional Ethics Committee (IEC) of the rural tertiary healthcare center. All participants provided written informed consent before enrollment.

Study setting and population

The study was conducted across all inpatient wards of a rural tertiary care hospital **(**Dr. Chandramma Dayananda Sagar Institute of Medical Education and Research (CDSIMER)) located in Ramanagara, Karnataka. The duration of the study was 05 months (from July 2024 to December 2024). The target population included adult patients from rural backgrounds, irrespective of their educational status, who were admitted to the hospital during the study period.

Inclusion and exclusion criteria

Participants aged between 18 and 75 years of either gender, willing to participate, and capable of providing informed consent were included in the study. Individuals who were healthcare workers or who declined to participate were excluded.

Sampling method and sample size

A convenient sampling method was used to recruit participants meeting the eligibility criteria. The sample size was determined using the formula, where Z=3.29 (for 99.9% confidence level), p=0.042 (considering 50% of the 8.4% prevalence reported in earlier studies), q=1−p=0.958, and e=0.05 (margin of error).

$$n = \frac{Z^2 \times p \times (1-p)}{e^2}$$

Based on the calculation, the required sample size was approximately 175 participants. However, additional 5 participants were enrolled as permitted by the study duration.

Study tools and intervention

A pre-validated questionnaire assessing KAP related to pharmacovigilance and ADR reporting was employed. The tool encompassed domains related to awareness, attitude, and practical aspects of pharmacovigilance. The intervention consisted of a single-session educational module delivered by the principal investigator using a PowerPoint presentation. The content was simplified and tailored for a lay audience, emphasizing the importance of ADR reporting and how patients can contribute to drug safety.

Study procedure

Eligible patients were approached during their hospital stay and briefed about the study using a participant information sheet. After obtaining informed consent, they were administered the pre-intervention KAP questionnaire. Following this, an educational session was conducted, immediately after which the same questionnaire was re-administered to assess the change in responses. The questionnaires were filled manually and collected by the investigators.

Data management and statistical analysis

The collected data were entered into a secured, password-protected system with all personal identifiers masked to ensure confidentiality. Descriptive statistics such as mean, standard deviation, and proportions were used for data summarization. Analytical comparisons between pre- and post-intervention scores were performed using paired and unpaired t-tests as appropriate. A p value of less than 0.05

was considered statistically significant. All statistical analyses were conducted using GraphPad Instat3 software.

RESULTS

A total of 180 participants were included in the study. The demographic characteristics, including age and gender distribution, are summarized in Table 1. The mean age of participants was 40.15±15.30 years, ranging from 18 to 75 years, with a nearly balanced gender distribution (96 males, 84 females). There was no significant age difference between male and female participants (p=0.1258).

Educational and socioeconomic background

Participants came from diverse educational backgrounds (Table 1): 20% were illiterate, 6.7% had completed 1st–5th standard, 29.4% had studied up to 6th–10th standard, 33.3% completed pre-university (PUC), and 10.6% held a degree. Occupationally, 41.1% were self-employed, 33.9% were homemakers, 20.6% worked in offices or companies, while the rest were retired or students. Socioeconomic status assessment showed 7.2% belonged to the lower class (LC), 32.8% to the lower-middle class (LMC), 21.7% to the middle class (MC), 29.4% to the upper-middle class (UMC), and 8.9% to the upper class (UC).

Knowledge assessment pre- and post-intervention

The intervention significantly improved participants' knowledge of pharmacovigilance, particularly regarding the definition and necessity of reporting ADRs. Notably, awareness about what constitutes an ADR increased from 27.8% pre-intervention to 97.8% post-intervention, and belief in the universality of side effects rose from 20% to 98.9%**.** However, the understanding that all ADRs must be reported irrespective of severity improved only marginally from 31.1% to 34.4%**.** Full details are provided in Table 2.

Despite the educational session, awareness of the Government of India's ADR reporting program remained low, increasing slightly from 3.3% to 3.9%. Additionally, only 8 participants had any prior exposure to ADR-related information, with sources including newspapers (3), internet (3), and healthcare professionals (2).

Table 1: Demographic characteristics of study participants (n=180).

Parameters	Frequency (N)	Percentage
Age (Years)		
Mean±SD	-	40.15±15.30
Range	-	18–75
Gender		
Male	96	53.3
Female	84	46.7
Education		
Illiterate	36	20.0
1st–5th standard	12	6.7
6th–10th standard	53	29.4
PUC	60	33.3
Degree	19	10.6
Occupation		
Self-employed	74	41.1
Homemaker	61	33.9
Office/company worker	37	20.6
Retired	3	1.7
Student	5	2.8
Socioeconomic status		
Lower class (LC)	13	7.2
Lower-middle class	59	32.8
Middle class	39	21.7
Upper-middle class	53	29.4
Upper class	16	8.9

Attitudes and practices toward ADR reporting

The study revealed promising attitudes: before the intervention, 90.6% believed patients share responsibility in ADR reporting, which slightly increased post-intervention. Willingness to report ADRs in the future also improved from 95% to 96.1%. However, actual practice remained poor. None of the participants had ever filled an ADR form, either before or after the session. Similarly, only 7 participants (3.9%) reported experiencing an ADR, and none of these were officially reported. Most managed it themselves or discontinued treatment without medical advice (Tables 3 and 4).

Table 2: Changes in knowledge regarding ADRs before and after educational intervention (n=180).

Q. no.	Knowledge question	Correct pre-test N (%)	Correct post-test N (%)
K1	Have you heard of ADRs?	91 (50.6)	180 (100)
K2	Do all drugs produce the same effect in all patients? (correct: no)	36 (20.0)	178 (98.9)
K3	Can all drugs cause ADRs?	50 (27.8)	176 (97.8)
K4	Should all ADRs be reported, including mild ones?	56 (31.1)	62 (34.4)
K5	Is ADR reporting only for doctors? (correct: no)	60 (33.3)	121 (67.2)
K6	Can pharmacists report ADRs?	69 (38.3)	155 (86.1)

Continued.

Q. no.	Knowledge question	Correct pre-test N (%)	Correct post-test N (%)
K7	Have you heard about India's official ADR monitoring program (PvPI)?	6 (3.3)	7 (3.9)
K8	Are patients allowed to report ADRs directly?	46 (25.6)	143 (79.4)
K9	Is there a specific form or method for ADR reporting? (e.g., yellow card/form)	8 (4.4)	137 (76.1)

Table 3: Practice-related responses of participants on ADR reporting (n=180).

Q. no.	Practice question	Response option	Frequency (N)	Percentage
P1	Have you ever experienced an ADR?	Yes	7	3.9
		No	173	96.1
P2	What action did you take for the ADR? (asked only to P1=yes, n=7)	Stopped treatment	3	42.9
		Ignored it	2	28.6
		Took home remedies	1	14.3
		Changed medicine after consultation	1	14.3
P3	Have you ever reported the ADR to a healthcare provider?	Yes	0	0
		No	7	100
P4	If given a chance, would you report an ADR in the future?	Yes	180	100
P5	Whom would you prefer to report the ADR to?	Doctor	136	75.6
		Nurse	32	17.8
		Pharmacist	12	6.6
P6	What method would you prefer to report the ADR?	In-person reporting	97	53.9
		By phone	38	21.1
		Using a reporting box	31	17.2
		Through mobile app or email	14	7.8

Table 4: Attitude-based responses on ADR reporting (n=180).

Q. no.	Attitude question	Response option	Frequency (N)	Percentage
A1	Do you think ADRs should be reported?	Yes	178	98.9
		No	2	1.1
A2	Is ADR reporting a professional obligation of healthcare providers?	Yes	179	99.4
		No	1	0.6
A3	Should patients be educated about ADRs and how to report them?	Yes	178	98.9
		No	2	1.1
A4	Do you think your ADR reporting could contribute to improving drug safety in India?	Yes	176	97.8
		No	4	2.2

Understanding roles in ADR reporting

Knowledge about who is responsible for ADR reporting was substantially improved post-intervention. Initially, only 3.3% identified healthcare workers as responsible.

Post-intervention, 66.7% correctly identified healthcare professionals, while 17.8% expanded their response to include ASHA workers, pharmacists, and the public. These results are detailed in Table 5.

Table 5: Understanding about persons responsible for ADR reporting (n=180).

Option selected	Pre-intervention N (%)	Post-intervention N (%)
Healthcare workers (doctors/nurses)	6 (3.3)	120 (66.7)
Pharmacists	2 (1.1)	22 (12.2)
ASHA workers	1 (0.6)	6 (3.3)
Public/patients	2 (1.1)	32 (17.8)
Not sure	166 (92.2)	0 (0)

DISCUSSION

The present study highlights the significant role of educational interventions in enhancing patient awareness (KAP) toward pharmacovigilance and ADR reporting. The findings reinforce existing literature that indicates a prevailing lack of awareness among patients regarding their role in pharmacovigilance.

Prior to the intervention, knowledge regarding ADR reporting mechanisms was markedly low, which aligns with earlier studies from Lithuania, Malaysia, and Portugal that reported poor consumer awareness about ADR reporting systems.[7,10,11]

Our study observed a statistically significant improvement in all three domains knowledge, attitude, and practice post-intervention, suggesting that even a single, structured educational session can have a tangible impact. This is corroborated by findings from a similar intervention-based study conducted in rural Nepal, where educational efforts led to improved KAP among pharmacists.[8]

Interestingly, the study population, which predominantly consisted of rural inpatients, showed enthusiasm in learning about ADR reporting once provided with accessible and simplified information. This mirrors observations from the Warsaw study, where a majority of patients believed that consumers shared an equal responsibility in pharmacovigilance.[9]

Barriers such as lack of time, understanding, and the assumption that only healthcare professionals are responsible for reporting were overcome by using simplified language and visual presentations in our educational module.[13,14] The success of this approach emphasizes the need for widespread, patient-centered pharmacovigilance awareness campaigns, especially in rural settings where underreporting is more pronounced.[15]

The encouraging post-intervention results underline a critical yet often overlooked aspect of pharmacovigilance: patient empowerment. With India contributing less than 1% to global ADR reports despite its massive pharmaceutical usage, engaging the general public could be a game-changer.[16] A system that enables, educates, and encourages patients to report ADRs could substantially improve national drug safety data and ultimately enhance patient care.

Limitations

This study's findings are constrained by several factors, including its single-center rural setting, which limits generalizability. The convenience sampling method may introduce selection bias, and the short-term assessment does not capture long-term impact. Additionally, reliance on self-reported data may lead to social desirability bias. The intervention's single-format delivery limits exploration of more diverse educational methods.

CONCLUSION

This study demonstrates that a brief, targeted educational intervention significantly improves the knowledge, attitude, and practice of inpatients toward ADR reporting. Given the underutilization of consumer pharmacovigilance in India, such initiatives could bridge the existing gap between drug consumption and safety surveillance. Incorporating pharmacovigilance education into routine inpatient care or community outreach programs could empower patients, increase reporting rates, and strengthen the overall pharmacovigilance system. Future efforts should focus on scalability and sustainability of such interventions to establish a culture of shared responsibility in drug safety monitoring.

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REFERENCES

1. Kommu S, Carter C, Whitfield P. Adverse Drug Reactions. In: StatPearls. Treasure Island (FL): StatPearls Publishing. 2024.
2. Doshi N, Prajapati B, Selvaraj L. A Pharmacovigilance Study on Adverse Drug Reaction Profile at a Tertiary Care Teaching Hospital from Western Part of India. Int J Pharm Investig. 2025;15(2):562-72.
3. Tandon VR, Mahajan V, Khajuria V, Gillani Z. Under-reporting of adverse drug reactions: a challenge for pharmacovigilance in India. Indian J Pharmacol. 2015;47(1):65-71.
4. Suke SG, Kosta P, Negi H. Role of Pharmacovigilance in India: An overview. Online J Public Health Inform. 2015;7(2):e223.
5. 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;8(3):158-63.
6. Kumar R Sr, Jindal A Sr, Garg P, Kaur A, Kumar S, Tilak Raj R, et al. Pharmacovigilance Study of Anticancer Drugs in a Tertiary Care Teaching Hospital in North India: A Retrospective Study. Cureus. 2023;15(9):e44984.
7. Valinciute A, Gerbutaviciene RJ, Paukstaitiene R, Kubiliene L. Pharmacovigilance and Adverse Drug Reaction Reporting among the General Public in Lithuania: A Cross-Sectional Study. Healthcare. 2023;11(8):1133.

8. Jha N, Rathore DS, Shankar PR, Bhandary S, Pandit RB, Gyawali S, et al. Effect of an educational intervention on knowledge and attitude regarding pharmacovigilance and consumer pharmacovigilance among community pharmacists in Lalitpur district, Nepal. BMC Res Notes. 2017;10(1):4.
9. Staniszewska A, Dąbrowska-Bender M, Olejniczak D, Duda-Zalewska A, Bujalska-Zadrożny M. Patient knowledge on reporting adverse drug reactions in Poland. Patient Prefer Adherence. 2016;11:47-53.
10. Matos C, van Hunsel F, Joaquim J. Are consumers ready to take part in the Pharmacovigilance System?--a Portuguese preliminary study concerning ADR reporting. Eur J Clin Pharmacol. 2015;71(7):883-90.
11. Mohammad A, Bheemavarapu H, Khan MU, Khan A, Ahmad A, Hassali MAA, et al. A cross-sectional survey to assess the knowledge, attitudes and common barriers to the reporting of adverse drug reactions by the general public in Malaysia. J Pharm Pract Res. 2018;48:348-55.
12. 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.
13. Ian Osoro N, Suhaib KP, Jamuna Rani R, Rajanandh MG. Barriers to and facilitators of healthcare professionals in ADR reporting in a tertiary care hospital in India. BMC Health Serv Res. 2025;25(1):166.
14. Shabaraya AR, Gautham JB, Tantry SK. A Study On Barriers Towards Reporting of Adverse Drug Reactions Among Healthcare Professionals, Clinical Management, and Drug Development. Int J Pharm Sci. 2024;2(8):3861-7.
15. Smith MY, Benattia I. The Patient's Voice in Pharmacovigilance: Pragmatic Approaches to Building a Patient-Centric Drug Safety Organization. Drug Saf. 2016;39(9):779-85.
16. Shukla S, Sharma P, Gupta P, Pandey S, Agrawal R, Rathour D, et al. Current Scenario and Future Prospects of Adverse Drug Reactions (ADRs) Monitoring and Reporting Mechanisms in the Rural Areas of India. Curr Drug Saf. 2024;19(2):172-90.

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