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Research Article

Enhancing Knowledge and Practical Competency in Adverse Drug Reaction Reporting Among Postgraduate Residents: A Pre-Post Interventional Study

Shoebul Haque[1*], Fatima Khan[2], Afroz Abidi[3]
[1*]Assistant Professor, Department of Pharmacology, Era's Lucknow Medical College & Hospital, Lucknow, U.P., India.
[2]Assistant Professor, Department of Pharmacology, Era's Lucknow Medical College & Hospital, Lucknow, U.P., India.
[3]Professor & Head, Department of Pharmacology, Era's Lucknow Medical College & Hospital, Lucknow, U.P., India.
Email: [1]shoeb_ulhaque@yahoo.com, [2]drfatimakhan@hotmail.com, [3]afrozabidi@gmail.com
Corresponding Author: Shoebul Haque
Assistant Professor, Department of Pharmacology, Era's Lucknow Medical College & Hospital, Lucknow, U.P., India.
E-mail: shoeb_ulhaque@yahoo.com
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ABSTRACT

Background: Adverse drug reaction (ADR) reporting is an important component of pharmacovigilance and patient safety. However, underreporting remains a significant challenge, often due to inadequate knowledge and training among healthcare professsionals. Educational interventions have been shown to improve awareness and reporting practices.

Objective: To evaluate the effectiveness of a structured educational intervention on knowledge and practical skills related to ADR reporting among postgraduate (PG) medical students.

Methods: A prospective interventional study was conducted among 70 first-year postgraduate students from various clinical and paraclinical departments. Participants underwent a pre-test assessment consisting of a structured 50-item multiple-choice questionnaire (MCQs) and ADR form-filling evaluation. A post-test was conducted using the same assessment tools. Data were analyzed using descriptive statistics, and the Wilcoxon signed-rank test was applied to compare pre and post-intervention scores. Effect size (r) and difficulty index (P) for MCQs were also calculated.

Results: The mean score increased from 23.5 in the pre-test to 32.5 in the post-test, with an average improvement of 8-10 marks. A significant improvement in overall performance was observed, with 96% of students showing score enhancement. The Wilcoxon signed-rank test demonstrated a statistically significant difference ($p < 0.001$), with a large effect size ($r = 0.79$). MCQ analysis revealed a shift from predominantly difficult and moderate questions in the pre-test to mostly easy questions in the post-test. Practical skills in ADR form filling also improved substantially.

Conclusion: The educational intervention significantly improved both knowledge and practical competencies related to ADR reporting among postgraduate students. Regular training programs and integration of pharmacovigilance education into postgraduate curricula are recommended to enhance ADR reporting practices and improve patient safety.

Keywords: Adverse Drug Reaction, Pharmacovigilance, PG Residents, Educational Intervention, ADR Reporting.

INTRODUCTION

Adverse drug reactions (ADRs) represent a significant and ongoing challenge in global healthcare, contributing substantially to patient morbidity, prolonged hospital stays, and, mortality.[1] With the increasing complexity of pharmacotherapy and the widespread use of polypharmacy, the occurrence of ADRs has become more pronounced.[2] Ensuring patient safety, therefore, requires not only appropriate prescribing practices but also robust systems for identifying and monitoring adverse effects associated with medications.[3] Pharmacovigilance plays a central role in

safeguarding public health by enabling the detection, assessment, understanding, and prevention of ADRs.[4] Programme relies heavily on spontaneous reporting systems, where healthcare professionals contribute by documenting and reporting suspected ADRs.[5] However, despite the existence of well-established pharmacovigilance frameworks globally, underreporting of ADRs remains a major limitation.[6] Studies have consistently shown that only a small fraction of actual ADRs are reported, thereby limiting the effectiveness of pharmacovigilance programs in identifying potential safety signals and preventing harm.[7] The Pharmacovigilance Programme of India (PvPI) has been implemented to strengthen drug safety monitoring across the country.[8] It provides a structured platform for reporting ADRs through designated Adverse Drug Reaction Monitoring Centres (AMCs) and standardized reporting forms.[9] Despite these efforts, the reporting rate among healthcare professionals continues to be suboptimal.[10] Several factors contribute to this issue, including lack of awareness, inadequate training, uncertainty about what and how to report, time constraints, and misconceptions regarding the importance of reporting non-serious or already known ADRs.[11] Postgraduate (PG) residents are integral to the healthcare delivery system, as they are actively involved in patient management across various clinical settings.[12] Their frequent patient interactions and involvement in prescribing and monitoring therapies place them in a unique position to identify and report ADRs.[13] However, their knowledge and practices related to pharmacovigilance are often influenced by the level of formal training they receive during their medical education. In many cases, pharmacovigilance training is limited or insufficient in both undergraduates and postgraduates, resulting in gaps in both theoretical understanding and practical application.[14] Educational interventions have been recognized as an effective strategy to address these gaps.[15] Structured training programs that combine didactic lectures with practical demonstrations and hands-on exercises can significantly enhance awareness, knowledge, and reporting behavior among doctors.[16] Such interventions not only clarify fundamental concepts, such as types of ADRs, causality assessment, and reporting criteria, but also build confidence in completing ADR reporting forms accurately.[17] Moreover, incorporating real-life scenarios and practice-based learning can further reinforce these skills and encourage active participation in pharmacovigilance activities.[18] The critical role of PG residents during ADR reporting practices, it is essential to evaluate the impact of targeted educational interventions in this group.[19] Assessing both knowledge and practical skills before and after training provides valuable insights into the effectiveness of such programs and helps identify areas that require further emphasis.[20] In addition, analyzing response patterns can highlight specific domains where misconceptions or knowledge gaps persist.[21] In this context, the present study was designed to assess the effectiveness of a structured training program on ADR reporting among postgraduate residents. The program included focused lectures on types of ADRs and the process of ADR reporting, along with hands-on training in filling ADR reporting forms.

MATERIALS AND METHODS

Study Design and Setting

A quasi-pre-post interventional study was conducted at Era's Lucknow Medical College and Hospital.

Primary Objective

- To evaluate the effectiveness of an educational intervention in improving knowledge and practical skills related to adverse drug reaction (ADR) reporting among first-year postgraduate medical students.

Secondary Objectives

- To compare pre-test and post-test scores of participants following the educational intervention.
- To assess improvement in practical competency in filling the Suspected ADR Reporting Form (SADRRF).
- To analyze question-wise performance using the difficulty index of MCQs.
- To determine the proportion of students demonstrating improvement after the intervention.
- To evaluate department-wise variations in performance among postgraduate students.

Study Participants

A total of 70 postgraduate (PG) residents from various clinical and paraclinical departments participated in the study.

Inclusion Criteria

1. All newly admitted first-year postgraduate (PG) resident doctors
2. Residents from all clinical, para-clinical, and pre-clinical specialties
3. Residents who were present during both pre-test and post-test sessions

Exclusion Criteria

1. Residents absent during either the pre-test or post-test
2. Participants with incomplete or improperly filled questionnaires
3. Those who were not able to attend the workshop due to intensive care unit/Emergency/Night duties

Study Instrument (Study Tool)

A structured, predesigned questionnaire was developed based on previously published studies and standard pharmacovigilance guidelines. The questionnaire was reviewed by subject experts in pharmacology and pharmacovigilance to ensure face and content validity.

The assessment consisted of two components:

1. Knowledge Assessment (MCQs)

A set of 50 multiple-choice questions (MCQs) was designed using Google Forms/Sheets to evaluate participants' knowledge regarding adverse drug reaction (ADR) reporting and pharmacovigilance. Each correct response was awarded 1 mark, while incorrect responses were assigned 0 marks.

2. Skill Assessment (ADR Reporting Form Filling)

Participants' practical skills in completing the Suspected ADR Reporting Form (SADRRF) were also assessed. The form comprised four sections (A-D), with each section scored as 10 marks for correct completion, 5 marks for partial completion, and 0 marks for incorrect or incomplete entries. This evaluation measured the participants' ability to apply their knowledge in practical pharmacovigilance settings.

Educational Intervention

Before the intervention, participants were briefed about the study objectives. The educational intervention was conducted as a structured interactive training session on pharmacovigilance and ADR reporting. The intervention included:

Didactic lecture Session: Covered essential concepts such as types of ADRs, importance of pharmacovigilance, Pharmacovigilance Programme of India (PvPI), reporting procedures, and roles of healthcare professionals.

Case-Based Discussion: Two realistic clinical scenarios were used to enhance understanding of ADR identification and reporting.

Hands-on Training: Participants were trained on how to fill the Suspected ADR Reporting Form (SADRRF), including explanation of various sections and terminologies. The total duration of the intervention was approximately 4 hours, ensuring active participation and interactive learning.

Procedure

The study was conducted in three phases: pre-intervention assessment, educational intervention, and post-intervention assessment. Initially, participants were briefed about the study objectives, followed by a pre-test to assess baseline knowledge and practical skills related to ADR reporting. Knowledge was evaluated using a structured 50-item MCQ questionnaire, while practical skills were assessed through completion of a Suspected ADR Reporting Form (SADRRF) based on a clinical scenario. Subsequently, participants underwent a structured educational intervention lasting approximately 2-3 hours, which included lectures on pharmacovigilance, ADR reporting guidelines, and the Pharmacovigilance Programme of India (PvPI). This was complemented by demonstration of ADR form filling and case-based discussions to enhance practical understanding. A post-test was conducted immediately after the intervention using the same assessment tools to ensure comparability. MCQs were scored as one mark for correct responses and zero for incorrect answers. The ADR form was evaluated section-wise, with scores assigned as 10 for correct, 5 for partially correct, and 0 for incorrect or incomplete responses. This approach enabled comprehensive assessment of both knowledge and practical skill improvement following the intervention.

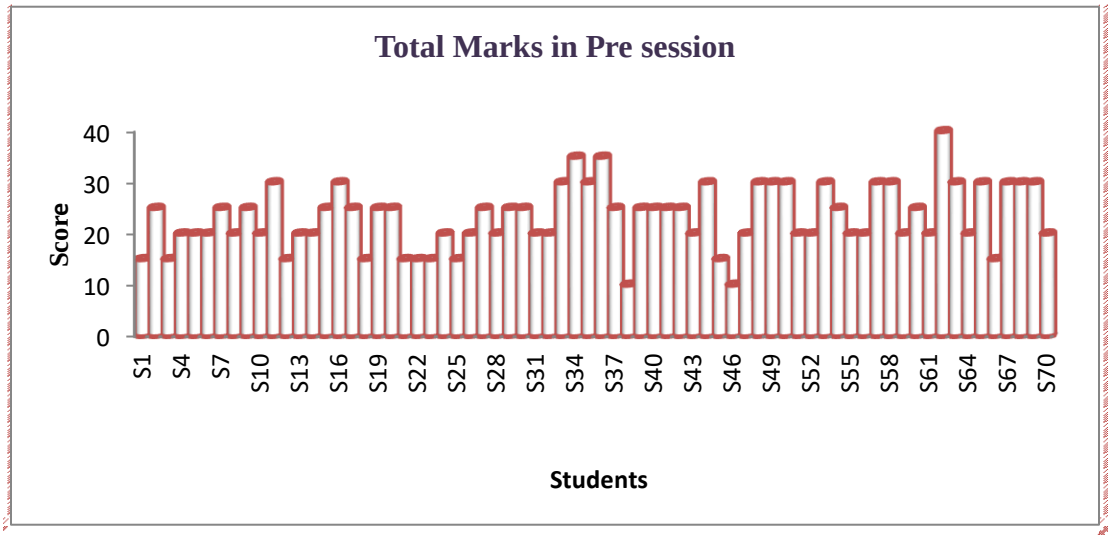
Statistical Analysis

Data were entered and analyzed by using Microsoft excel. Descriptive statistics, including mean, median, standard deviation, and percentages, were calculated to summarize the data. The Wilcoxon signed-rank test was used to compare paired pre-test and post-test scores, as the data were not normally distributed. The magnitude of the intervention effect was assessed by calculating the effect size (r). The difficulty index (P) for each question was calculated using the formula: number of correct

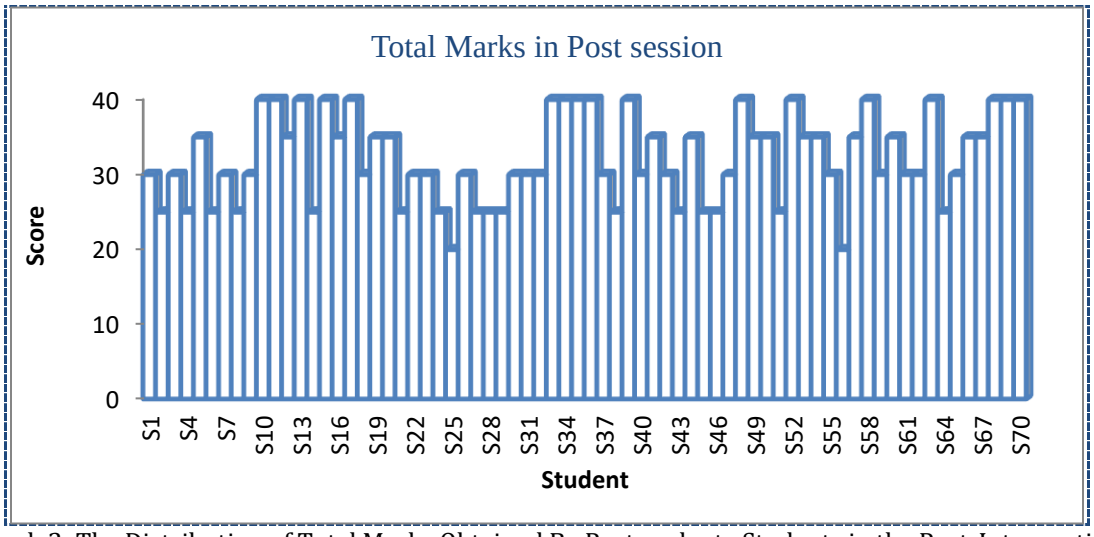
responses divided by the total number of students. Based on the calculated values, questions were categorized as easy (P > 0.75), moderate (P = 0.50–0.75), or difficult (P < 0.50). A p-value < 0.05 was considered statistically significant.

RESULTS

The graphical representation below illustrates the distribution of marks obtained by students in each section of the ADR reporting form. The distribution of total marks obtained by students in the pre-intervention assessment is presented in Graph 1. It reflects the baseline knowledge and practical skills of participants in ADR reporting. The post-intervention performance of students is illustrated in Graph 2, which shows a clear improvement in total scores following the educational intervention.



Graph 1: The Distribution of Total Marks Obtained By Postgraduate Students in the Pre-Intervention Assessment of ADR Form Filling



Graph 2: The Distribution of Total Marks Obtained By Postgraduate Students in the Post-Intervention Assessment of ADR Form Filling

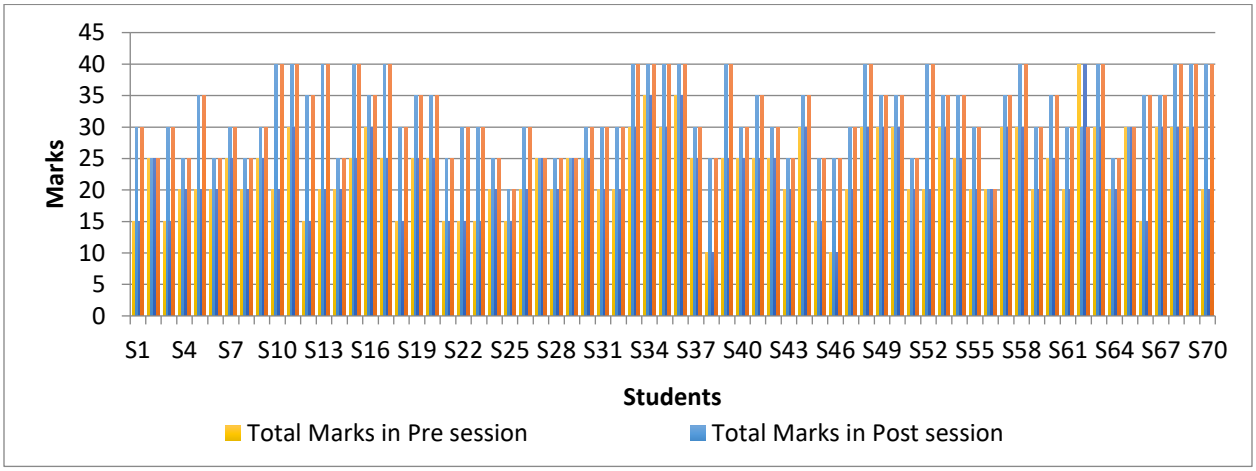
Mean Improvement Estimate for Each Student

The mean score of students increased from approximately 23-25 in the pre-intervention assessment to around 32-35 in the post-intervention assessment. This reflects an average improvement of about 8-10 marks per student.

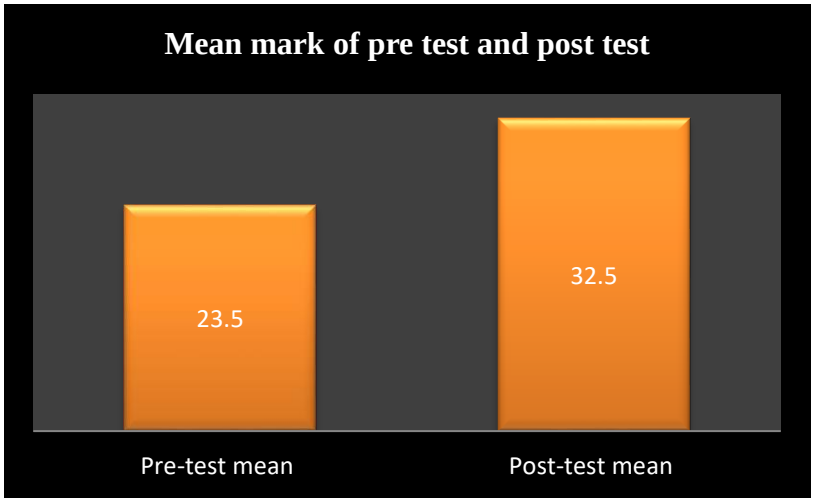
Considering the total score was 40, this improvement is substantial and corresponds to an approximate performance gain of 20–25%. As shown in Table 1, the mean score increased from 23.5 in the pre-test to 32.5 in the post-test, demonstrating a clear improvement in knowledge and practical competency following the educational intervention.

Table 1: Comparison of Pre-test and Post-test Mean Scores of ADR form filling test

Test	Mean mark
Pre-test mean	23.5
Post-test mean	32.5



Graph 3: Showing the Students Score in Pre-Test And Post-Test of ADR Form Filling Test



Graph 4: Showing The Mean Mark Of Pre-Test And Post-Test Of ADR Form Filling Test

Graph 3 depicts the comparison of individual student scores in the pre-test and post-test, highlighting a general upward trend in performance after the intervention. Graph 4 illustrates the mean scores of the pre-test and post-test, showing a marked improvement in average performance following the educational session.

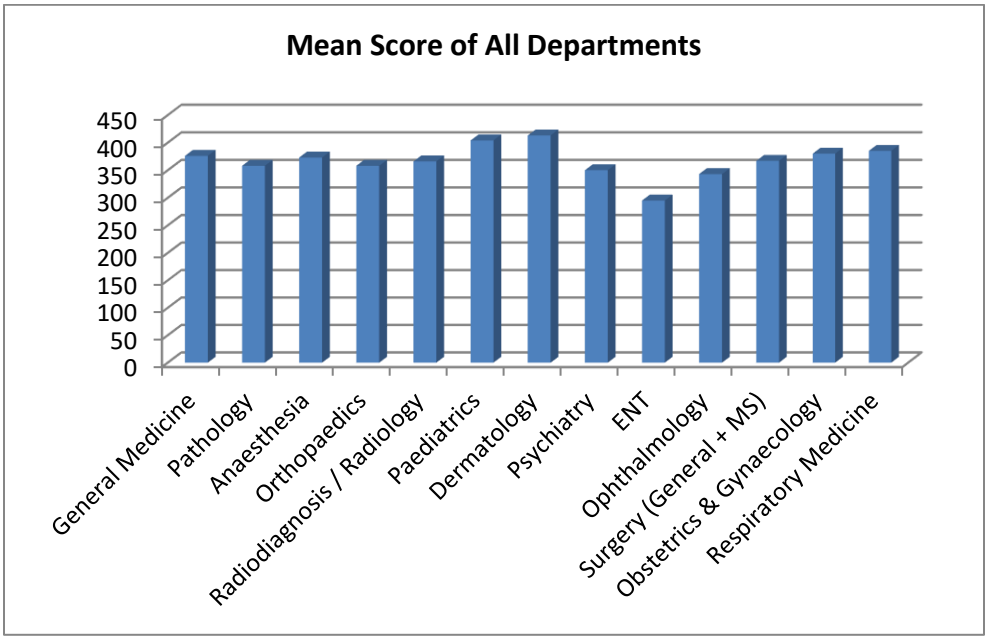
Performance Consistency in Pre-Test and Post-Test of ADR Form Filling

A total of 39 out of 70 students achieved scores of ≥25 in both the pre-test and post-test assessments. This indicates that approximately 55.7% of the participants maintained a consistently good level of performance throughout the study. The remaining students, who scored below 25 in the pre-test, showed

improvement in the post-test following the educational intervention. These findings suggest that while a substantial proportion of students already had adequate baseline knowledge, the intervention was effective in enhancing the performance of those who initially scored lower. Department-wise analysis revealed variability in performance as shown in table 2, with Dermatology and Paediatrics showing the highest scores, while ENT had the lowest.

Table 2: Department wise mean score of MCQ-test

Department	Mean Score (out of 500)
General Medicine	376
Pathology	358
Anesthesia	373
Orthopedics	358
Radiodiagnosis / Radiology	366
Paediatrics	404
Dermatology	413
Psychiatry	350
ENT	295
Ophthalmology	343
Surgery (General + MS)	367
Obstetrics & Gynecology	380
Respiratory Medicine	385



Graph 5: The Mean Scores of all Post-Graduates from the Various Departments

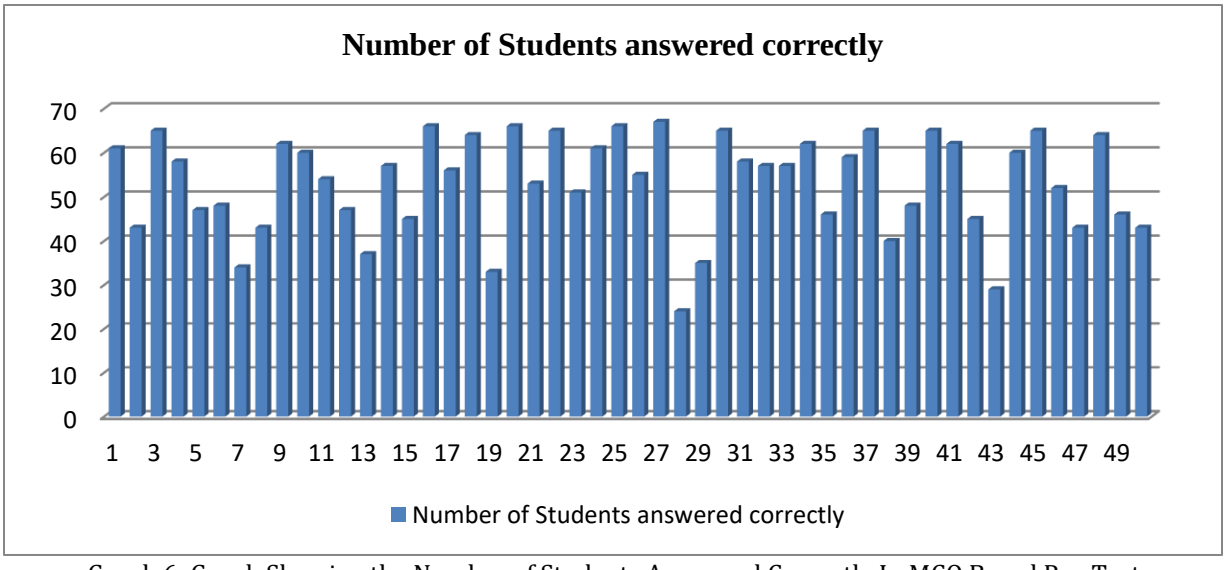
Graph 5 represents the department-wise mean scores (out of 500) showed noticeable variation in performance. Dermatology (413) and Paediatrics (404) recorded the highest scores, followed by Obstetrics & Gynecology (380) and Respiratory Medicine (385). General Medicine, Anesthesia, Surgery, and Radiology demonstrated consistent mid-to-high performance, while Pathology, Orthopedics, Psychiatry, and Ophthalmology showed moderate scores. ENT had the lowest mean score (295). Overall, while most departments performed within a similar range, certain specialties showed superior performance, whereas others may require additional academic focus.

Difficulty Level of Questions in the Pre-test of MCQ based assessment

The difficulty level of individual questions in the pre-test was assessed based on the number of students who answered each question correctly. Table 3 presents the distribution of correct responses for all questions, which was used to determine the relative difficulty of each item. Questions with a higher number of correct responses were considered easy, whereas those with fewer correct responses were categorized as difficult. This analysis provides insight into the baseline understanding of participants and helps identify areas requiring further emphasis during the educational intervention.

Table 3: The Number of Students Answered the Questions Correctly in MCQ Based Pre-Test

Question No.	Correct Responses	Question No.	Correct Responses	Question No.	Correct Responses
1	61	18	64	35	46
2	43	19	33	36	59
3	65	20	66	37	65
4	58	21	53	38	40
5	47	22	65	39	48
6	48	23	51	40	65
7	34	24	61	41	62
8	43	25	66	42	45
9	62	26	55	43	29
10	60	27	67	44	60
11	54	28	24	45	65
12	47	29	35	46	52
13	37	30	65	47	43
14	57	31	58	48	64
15	45	32	57	49	46
16	66	33	57	50	43
17	56	34	62	—	—



Graph 6: Graph Showing the Number of Students Answered Correctly In MCQ Based Pre-Test

The analysis of question-wise performance revealed variability in the level of understanding among participants in Graph 6. The question 28 on the commonly used causality assessment tool in India was found to be one of the most difficult, indicating limited awareness in this area. In

contrast, Question 27, which asked "If an ADR occurs in a private clinic," was answered correctly by the majority of students, with the correct response being that it should be reported to the nearest Adverse Drug Reaction Monitoring Centre (AMC). This indicates that participants had better awareness of basic reporting responsibilities compared to more complex concepts like causality assessment.

Inferential Analysis of Pre- and Post-Intervention Scores of MCQ based assessment

A total of 70 postgraduate students participated in both pre-test and post-test assessments. The analysis demonstrated a clear improvement in scores following the educational intervention. The mean score increased from 359.71 in the pre-test to 439.86 in the post-test. Similarly, the median score improved from 360 to 460, indicating a substantial rise in central tendency of approximately 80 points. Out of the 70 participants, 67 showed improvement in their scores, while 3 participants showed no change. Only a small proportion of students demonstrated a decline in scores. The Wilcoxon signed-rank test was applied to assess the significance of the observed difference. The test revealed a statistically highly significant improvement in post-test scores (W = 108.0, Z = −6.44, p < 0.001), indicating that the intervention had a significant effect on student performance. Furthermore, the calculated effect size (r = 0.79) indicates a very large effect, suggesting that the educational intervention had a strong and meaningful impact on both knowledge and practical skills related to ADR reporting.

Wilcoxon Signed-Rank Test (Precise Computation)

W (test statistic) equals 108.0
Z-value = −6.44 p-value = p < 0.001
(n) non-zero pairings = 67

Effect Size

$$r = \frac{Z}{\sqrt{N}} = \frac{6.44}{\sqrt{67}} = 0.79$$

- **Effect size (r)** = **0.79**

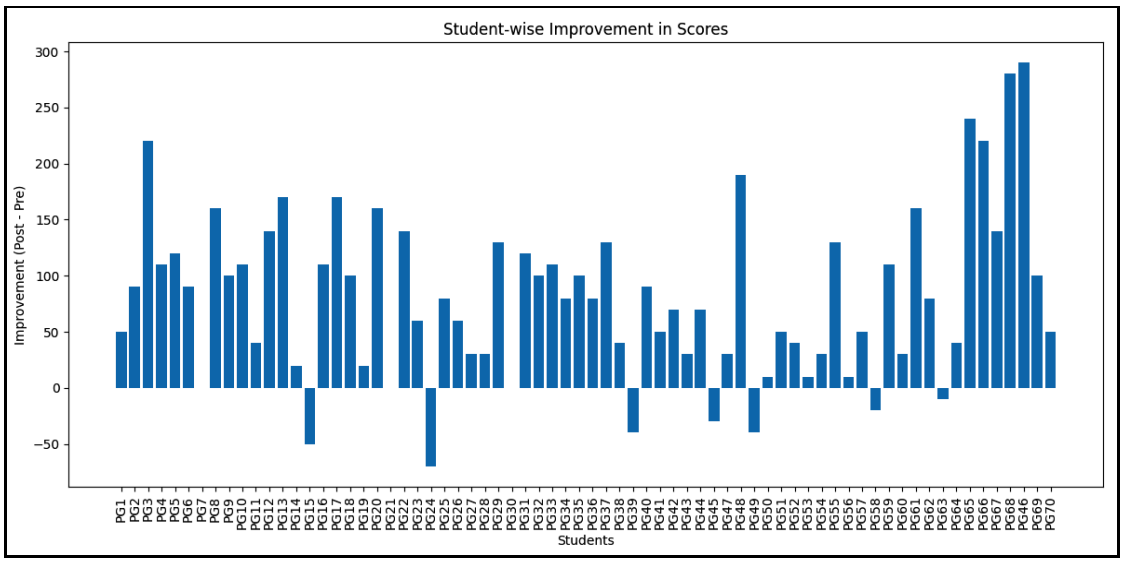
Interpretation: 0.79 = Very large effect size

A majority of participants (approximately 96%) showed improvement in their scores, with only a few students demonstrating no change or a slight decline. The Wilcoxon signed-rank test revealed a statistically highly significant difference between pre-test and post-test scores (p < 0.001), confirming the effectiveness of the intervention. The calculated effect size (r = 0.79) indicated a very large impact, suggesting that the educational intervention had a strong influence on improving students' knowledge and performance in ADR reporting.

Table 4: Comparison of Pre-test, Post-test MCQs, and Improvement Scores of Students

Student	Pre	Post	Improve-ment	Student	Pre	Post	Improve-ment	Student	Pre	Post	Improve-ment
PG1	120	170	50	PG25	390	470	80	PG49	420	380	-40
PG2	400	490	90	PG26	410	470	60	PG50	360	370	10
PG3	270	490	220	PG27	410	440	30	PG51	360	410	50
PG4	370	480	110	PG28	280	310	30	PG52	440	480	40
PG5	360	480	120	PG29	370	500	130	PG53	380	390	10
PG6	400	490	90	PG30	340	340	0	PG54	340	370	30
PG7	450	450	0	PG31	360	480	120	PG55	370	500	130
PG8	320	480	160	PG32	320	420	100	PG56	410	420	10

PG9	390	490	100	PG33	370	480	110	PG57	430	480	50
PG10	360	470	110	PG34	300	380	80	PG58	440	420	-20
PG11	370	410	40	PG35	360	460	100	PG59	340	450	110
PG12	360	500	140	PG36	420	500	80	PG60	420	450	30
PG13	330	500	170	PG37	350	480	130	PG61	250	410	160
PG14	470	490	20	PG38	370	410	40	PG62	350	430	80
PG15	450	400	-50	PG39	420	380	-40	PG63	440	430	-10
PG16	330	440	110	PG40	350	440	90	PG64	410	450	40
PG17	290	460	170	PG41	350	400	50	PG65	240	480	240
PG18	340	440	100	PG42	350	420	70	PG66	280	500	220
PG19	470	490	20	PG43	430	460	30	PG67	360	500	140
PG20	310	470	160	PG44	430	500	70	PG68	200	480	280
PG21	400	400	0	PG45	440	410	-30	PG46	210	500	290
PG22	350	490	140	PG47	130	160	30	PG69	390	490	100
PG23	330	390	60	PG48	290	480	190	PG70	440	490	50
PG24	420	350	-70	—	—	—	—	—	—	—	—



Graph 7: Bar Graph Illustrating Student-Wise Improvement in Scores between Pre-Test and Post-Test Assessments

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The majority of postgraduate students (n = 63) demonstrated improvement in their scores following the intervention, while 3 students (PG7, PG21, PG30) showed no change. A small number of students exhibited a decline in scores, although the reductions were minimal. The highest improvements were observed in PG46, PG68, PG65, PG3, and PG66, indicating substantial learning gains. In contrast, a few students with reduced scores may require additional support. Overall, the results indicate a strong trend toward improvement, with only minimal declines, suggesting that the intervention was largely effective.

Comparison of Difficulty Level of MCQs in Pre-test and Post-test

The difficulty level of multiple-choice questions (MCQs) was assessed using the Difficulty Index (P), calculated as:

$$\text{Difficulty Index (P)} = \frac{\text{Number of correct responses}}{\text{Total students}}$$

Difficulty Index (P)	Interpretation
> 0.75	Easy
0.50 – 0.75	Moderate
< 0.50	Difficult

Table 5: Interpretation of Difficulty Index for MCQs

In the pre-test, the majority of questions were categorized as moderate (50–75%) and difficult (<50%), with only a few questions falling under the easy category. This indicates that the baseline knowledge of students was limited, and several concepts were not well understood initially. In contrast, the post-test showed a clear shift, with most questions falling into the easy category (>75%), while only a few remained moderate and very few were still difficult. This suggests a considerable improvement in comprehension, indicating that the educational intervention was effective in clarifying most of the concepts.

Category	Pre-Test	Post-Test
Easy Questions	Few	Many
Moderate	Some	Few
Difficult	Many	Very Few

Table 6: Pre- and Post-Test Comparison of MCQ Difficulty Categories

Table 7: Comparison of Difficulty Index (P-Values) in Pre-Test And Post-Test

Question Number	Pre-test Difficulty Index	Level	Post-test Difficulty Index	Level
Q1	0.014	Difficult	0.014	Difficult
Q2	0.114	Difficult	0.157	Difficult
Q3	0.014	Difficult	0.014	Difficult
Q4	0.057	Difficult	0.057	Difficult
Q5	0.7	Moderate	0.871	Easy
Q6	0.614	Moderate	0.871	Easy
Q7	0.929	Easy	0.957	Easy
Q8	0.829	Easy	0.9	Easy
Q9	0.671	Moderate	0.871	Easy
Q10	0.686	Moderate	0.9	Easy
Q11	0.486	Difficult	0.843	Easy

Q12	0.629	Moderate	0.886	Easy
Q13	0.9	Easy	0.943	Easy
Q14	0.871	Easy	0.943	Easy
Q15	0.771	Easy	0.914	Easy
Q16	0.671	Moderate	0.829	Easy
Q17	0.529	Moderate	0.7	Moderate
Q18	0.814	Easy	0.9	Easy
Q19	0.643	Moderate	0.814	Easy
Q20	0.943	Easy	0.943	Easy
Q21	0.8	Easy	0.886	Easy
Q22	0.914	Easy	0.871	Easy
Q23	0.471	Difficult	0.686	Moderate
Q24	0.943	Easy	0.9	Easy
Q25	0.757	Easy	0.9	Easy
Q26	0.929	Easy	0.929	Easy
Q27	0.729	Moderate	0.957	Easy
Q28	0.871	Easy	0.914	Easy
Q29	0.943	Easy	0.943	Easy
Q30	0.786	Easy	0.9	Easy
Q31	0.957	Easy	0.943	Easy
Q32	0.343	Difficult	0.414	Difficult
Q33	0.5	Moderate	0.829	Easy
Q34	0.929	Easy	0.929	Easy
Q35	0.4	Difficult	0.757	Easy
Q36	0.786	Easy	0.857	Easy
Q37	0.814	Easy	0.843	Easy
Q38	0.886	Easy	0.9	Easy
Q39	0.657	Moderate	0.7	Moderate
Q40	0.843	Easy	0.843	Easy
Q41	0.929	Easy	0.886	Easy
Q42	0.571	Moderate	0.8	Easy
Q43	0.686	Moderate	0.943	Easy
Q44	0.929	Easy	0.929	Easy
Q45	0.886	Easy	0.943	Easy
Q46	0.643	Moderate	0.743	Moderate
Q47	0.414	Difficult	0.7	Moderate
Q48	0.457	Difficult	0.8	Easy
Q49	0.314	Difficult	0.757	Easy
Q50	0.729	Moderate	0.943	Easy

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In the pre-test, several questions were identified as difficult, including Q1, Q2, Q3, Q4, Q11, Q23, Q32, Q35, Q47, Q48, and Q49. Following the educational intervention, most of these questions showed improvement; however, Q1, Q3, Q4, and Q32 remained difficult, indicating the need for additional focus on these topics. A substantial improvement was observed in several questions that shifted from difficult to easy, reflecting strong learning gains after the intervention. Questions such as Q23 and Q47 showed moderate improvement, indicating partial understanding but suggesting that these areas were not yet fully mastered.

Table 8: Interpretation of MCQ Difficulty Levels in Pre- and Post-Test

Question	Pre-Test Level	Post-Test Level	Interpretation
Q1	Difficult	Difficult	No improvement (Needs attention)
Q2	Difficult	Difficult	Minimal improvement
Q3	Difficult	Difficult	No improvement
Q4	Difficult	Difficult	No improvement
Q5	Moderate	Easy	Improved
Q6	Moderate	Easy	Improved
Q7	Easy	Easy	Already known
Q8	Easy	Easy	Already known
Q9	Moderate	Easy	Improved
Q10	Moderate	Easy	Improved
Q11	Difficult	Easy	Strong improvement
Q23	Difficult	Moderate	Partial improvement
Q32	Difficult	Difficult	Still difficult
Q35	Difficult	Easy	Strong improvement
Q47	Difficult	Moderate	Partial improvement
Q48	Difficult	Easy	Strong improvement
Q49	Difficult	Easy	Strong improvement

Graph 8 demonstrate the comparison of difficulty index values and corresponding MCQ difficulty levels between the pre-test and post-test. A clear shift toward higher difficulty index values and an increased number of easy questions in the post-test indicates improved student understanding following the educational intervention.

DISCUSSION

The findings of the present study clearly indicate that a structured educational intervention is effective in enhancing both knowledge and practical competency related to adverse drug reaction (ADR) reporting among postgraduate residents. A marked improvement in post-intervention scores, which was statistically highly significant ($p < 0.001$), demonstrates that the observed changes were unlikely to be due to chance and can be attributed to the training provided. The magnitude of improvement, reflected by an average gain of 8–10 marks and a large effect size, further supports the strong

impact of the intervention. A notable observation was that the majority of participants showed improvement following the intervention, suggesting that structured teaching methods can effectively address existing gaps in pharmacovigilance knowledge. The improvement in performance aligns with findings from similar educational studies.[22] These studies have shown that targeted training can effectively increase awareness among healthcare professionals.[23][24] It also helps improve their ADR reporting practices. Analysis of individual questions using the difficulty index revealed a clear shift from predominantly difficult and moderate questions in the pre-test to mostly easy questions in the post-test. This transition reflects improved conceptual clarity among participants. Basic aspects of ADR reporting, such as identification and reporting responsibility, were well understood after the intervention. However, certain topics, particularly those involving causality assessment and more detailed regulatory concepts, remained relatively challenging. These findings suggest that while short-term interventions are effective, complex areas may require repeated exposure, reinforcement, and possibly advanced training modules.[25]

The inclusion of practical training in ADR form filling significantly contributed to skill development. The improvement observed in form-filling scores indicates that hands-on, application-based learning plays a crucial role in translating theoretical knowledge into clinical practice. This aspect is particularly relevant in pharmacovigilance, where accurate and complete reporting is essential. Overall, the results underscore the importance of integrating structured and interactive pharmacovigilance training into postgraduate medical education.

CONCLUSION

The present study shows that a structured training program can meaningfully improve both the knowledge and practical skills of postgraduate residents in ADR reporting. A clear and statistically significant improvement in scores was observed after the intervention, with most participants demonstrating noticeable learning gains. Despite this progress, certain advanced areas of pharmacovigilance still require better understanding, indicating the need for ongoing reinforcement. Therefore, regular training sessions and continuous medical education (CME) programs should be encouraged to strengthen ADR reporting practices and ultimately contribute to improved patient safety.

Limitations

This study has certain limitations that should be considered while interpreting the findings. It was conducted at a single center, which may limit the generalizability of the results to other settings. The assessment was carried out over a short duration, and therefore, long-term retention of knowledge and skills could not be evaluated. In addition, no follow-up was conducted to determine whether the improvement was sustained over time.

Future Perspectives

Incorporating regular and repeated training sessions, including refresher courses and continuous medical education (CME) programs, may further strengthen learning outcomes. In addition, integrating pharmacovigilance training into the routine postgraduate curriculum could ensure sustained improvement in awareness and practice. The use of digital tools, simulation-based learning, and real-time ADR reporting exercises may also enhance practical competency. Furthermore, future research should explore the actual impact of such interventions on real-world ADR reporting rates and patient safety outcomes.

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Conflict of Interest

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