e-ISSN: 0976-822X, p-ISSN:2961-6042

Available online on http://www.ijcpr.com/

International Journal of Current Pharmaceutical Review and Research 2026; 18(3); 1260-1268

Original Research Article

Knowledge, Attitude, and Practice of Materiovigilance Among Undergraduate Students: A Multicentric Cross-Sectional Observational Study

Roohi Sharma[1], Shivani Rani[2], Rachana Raina[3], Srishti Mantoo[4], Archana Parihar[5], Pavan Malhotra[6]

[1]Associate Professor, Department of Pharmacology, GMC Udhampur, J & K, India
[2]Assistant Professor, Department of Pharmacology, ASCOMS Jammu, J & K, India
[3]Senior Resident, Department of Pharmacology, GMC, Jammu, J & K, India
[4]Assistant Professor, Department of Pharmacology, ASCOMS Jammu, J & K, India
[5]Professor & Head, Department of Pharmacology, ASCOMS, Jammu, J & K, India
[6]Director Principal, ASCOMS, Jammu, J & K, India

Received: 26-01-2026 / Revised: 25-02-2026 / Accepted: 27-03-2026
Corresponding Author: Dr. Rachana Raina
Conflict of interest: Nil

Abstract:

Background: Materiovigilance plays an essential role in ensuring patient safety by identifying, reporting, and preventing adverse events associated with medical devices. As undergraduate students are future healthcare professionals, their knowledge, attitude, and practice regarding materiovigilance are important for strengthening reporting systems and promoting safe clinical care. However, awareness and practical exposure to materiovigilance among undergraduates remain limited.

Aim: To assess the knowledge, attitude, and practice of materiovigilance among undergraduate students at GMC Udhampur and ASCOMS Jammu and to determine the association of selected sociodemographic and training-related factors with these domains.

Material and Methods: A cross-sectional observational study was conducted among undergraduate students of a tertiary care hospital. Data were collected using a structured, prevalidated questionnaire consisting of sociodemographic details and items related to knowledge, attitude, and practice of materiovigilance. Responses were analyzed using descriptive and inferential statistics. Knowledge, attitude, and practice were graded into categories, and associations with variables such as academic year and prior training were assessed using appropriate statistical tests. A p value of less than 0.05 was considered statistically significant.

Results: Most participants were aged 20-22 years (59.00%), females constituted 57.00%, and final-year students formed the largest subgroup (45.00%). About 63.00% had heard of materiovigilance, while 77.00% were aware that medical devices can cause adverse events. However, only 42.00% knew about the Materiovigilance Programme of India, 34.00% were aware of designated reporting centers, and 26.00% knew about the reporting form or portal. Overall, 54.00% had moderate knowledge, 59.00% had a positive attitude, and 51.00% had poor practice. A large majority agreed that materiovigilance is important for patient safety (86.00%), reporting should be mandatory (82.00%), and undergraduate students should be trained in materiovigilance (90.50%). Only 9.00% had ever reported a device-related adverse event, 18.00% had received prior training, and 20.50% were familiar with the reporting form or portal. Significant associations were observed between academic year and knowledge level ($p = 0.003$), and between prior training and both knowledge ($p = 0.007$) and practice ($p = 0.001$).

Conclusion: Undergraduate students demonstrated moderate knowledge and a favorable attitude toward materiovigilance, but their reporting practice was inadequate. Limited procedural awareness and insufficient training appear to be major barriers. Incorporating formal materiovigilance teaching, practical demonstrations, and reporting sensitization sessions into undergraduate training may improve reporting competence and strengthen patient safety.

Keywords: Materiovigilance; Medical Device Adverse Events; Knowledge Attitude Practice; Undergraduate Students; Patient Safety.

DOI: 10.25258/ijcpr.18.3.202

Introduction

Patient safety has become a central concern in modern health care because the growing complexity of diagnosis, treatment, monitoring, and supportive care has increased dependence on medical technologies at every level of service delivery. From simple consumables and bedside instruments to implantable and life-supporting equipment, medical devices now influence nearly every clinical decision and patient encounter. Although these products improve precision, access, and outcomes, they can also contribute to harm when they malfunction, are used incorrectly, deteriorate during routine use, or fail because of design, maintenance, labeling, or system-level problems. For that reason, patient safety is no longer understood only as freedom from medication errors or procedural mistakes; it also includes the safe selection, operation, monitoring, and post-market evaluation of medical devices within real-world practice.[1] Unlike medicines, many medical devices are highly operator-dependent and perform differently across settings, users, and patient populations. Their safety profile may therefore evolve after widespread clinical use, when devices are exposed to varied environments, repeated handling, maintenance practices, and unexpected patterns of use. Adverse events related to medical devices may arise from technical defects, software issues, calibration errors, inadequate instructions for use, poor compatibility with accessories, human factors, or failure to recognize early warning signs of deterioration. Because such events are often multifactorial, they may remain unnoticed, misclassified, or underreported unless there is a structured surveillance system capable of collecting, analyzing, and communicating safety information. This need has made post-market surveillance and materiovigilance essential components of quality assurance in contemporary health systems. Materiovigilance refers to the systematic monitoring of adverse events and other safety concerns associated with medical devices, with the aim of reducing recurrence and improving patient protection. In India, the Materiovigilance Programme of India (MvPI) was developed to create a national framework for identifying, documenting, assessing, and communicating medical device–related adverse events. The programme seeks not only to support regulatory decision-making but also to promote a culture in which clinicians, nurses, pharmacists, biomedical engineers, technicians, manufacturers, and institutions actively participate in safety reporting. The Indian guidance framework emphasizes that materiovigilance is not limited to catastrophic device failure; it also includes near misses, performance problems, labeling deficiencies, and incidents that can inform preventive action before serious harm occurs. [2,3] An effective materiovigilance system depends on timely recognition of suspected device-related adverse events and on the willingness and ability of health-care personnel to report them correctly. Reporting is meaningful only when health professionals understand what constitutes a reportable event, where it should be reported, how reporting forms or portals are used, and why near misses matter for prevention. Hospital-based safety systems also need mechanisms for documentation, internal review, escalation, feedback, and coordination with regulatory structures. When these processes are weak, adverse events may remain confined to local experience, and opportunities for broader learning may be lost. Literature on device surveillance has repeatedly highlighted the importance of structured institutional systems, standard operating pathways, and feedback loops in strengthening vigilance practice. [4] Despite the recognized importance of reporting, underreporting remains a persistent challenge in medical device safety. Published work has shown that professionals may hesitate to report because of uncertainty about causality, limited awareness of reporting channels, fear of blame, lack of time, poor feedback, and ambiguity about roles and responsibility. Some events may be normalized as routine technical problems rather than recognized as safety incidents, especially in busy clinical environments where devices are handled by multiple categories of staff. In addition, adverse events involving devices may be mistaken for disease progression, operator error, or isolated technical glitches, reducing the likelihood that they enter a formal surveillance pathway. Recent research also suggests that organizational culture, regulatory clarity, and supportive leadership strongly influence whether reporting becomes routine or remains neglected. [5] These concerns make undergraduate health professional training particularly important. Students begin encountering medical devices early in clinical postings, simulation exercises, skill laboratories, ward procedures, and outpatient settings. Their first impressions about reporting, accountability, and patient safety are often formed during this training period. If undergraduate learners are exposed only to device use but not to device safety surveillance, they may graduate with limited ability to identify, document, and communicate adverse events. In contrast, early sensitization can help them view safety reporting as a professional responsibility rather than an optional administrative task. The competency-based undergraduate medical curriculum introduced in India has emphasized the development of appropriate knowledge, skills, attitudes, ethics, and communication, creating an educational context in which materiovigilance can be meaningfully integrated into patient safety learning. [6]

Material and Methods

This study was designed as a cross-sectional observational study to assess the knowledge, attitude, and practice of materiovigilance among undergraduate students at GMC Udhampur and ASCOMS Jammu. The study was conducted in the academic and clinical environment of the tertiary care teaching hospitals, where undergraduate students are exposed to patient care activities, medical devices, and hospital-based reporting systems. The institutional setting provided an appropriate platform to evaluate awareness and practices related to materiovigilance in a real-world healthcare training environment.

The study population comprised undergraduate students posted in the tertiary care hospital. A total of 200 participants were included in the study. The participants were selected to represent students from relevant undergraduate health science streams who had exposure to clinical teaching and hospital practices. The sample size of 200 was considered adequate to provide a meaningful assessment of the level of knowledge, attitude, and practice regarding materiovigilance among the target population.

Eligibility Criteria: Undergraduate students who were willing to participate and available at the time of data collection were included in the study. Students who had exposure to hospital or clinical postings and were able to understand and respond to the study questionnaire were considered eligible. Students who declined to participate, submitted incomplete questionnaires, or were absent during the data collection process were excluded from the study.

Methodology: Data were collected using a structured, self-administered questionnaire developed to assess the knowledge, attitude, and practice of materiovigilance. The questionnaire was prepared after reviewing relevant literature and standard concepts related to medical device safety monitoring and reporting. It consisted of four sections: sociodemographic details, knowledge-related items, attitude-related items, and practice-related items. The sociodemographic section included variables such as age, gender, academic year, and course of study. The knowledge domain included questions on awareness of materiovigilance, understanding of medical device adverse events, identification of reportable incidents, awareness of reporting centers, and knowledge of the national reporting system. The attitude domain evaluated perceptions regarding the importance of materiovigilance, responsibility of healthcare students in reporting adverse events, need for training, and willingness to participate in reporting systems. The practice domain included parameters such as previous observation of medical device-related adverse events, experience with reporting, familiarity with reporting forms or portals, participation in training programs, and actions taken after encountering a device-related problem.

Content validity and reliability of the questionnaire: The questionnaire was reviewed by subject experts in pharmacology, clinical practice, and research methodology to ensure content adequacy, clarity, and relevance. Necessary modifications were made based on expert suggestions to improve comprehensibility and appropriateness of the items. A pilot evaluation was carried out on a small group of students not included in the final analysis to assess the feasibility, readability, and internal consistency of the instrument. The final questionnaire was then used for data collection after ensuring that the items adequately captured the intended study objectives.

Study variables and scoring pattern: The primary study variables were knowledge, attitude, and practice related to materiovigilance. Knowledge was assessed through multiple objective items, with each correct response assigned a score of 1 and incorrect or unanswered responses assigned a score of 0. The total knowledge score was calculated by summing the individual item scores, and participants were categorized into poor, moderate, or good knowledge levels based on predefined score ranges. Attitude was measured using statements on a Likert scale ranging from strongly agree to strongly disagree, and the cumulative attitude score reflected the positivity of participant perception toward materiovigilance. Practice was assessed using response items related to actual exposure, reporting behavior, and participation in device safety monitoring activities, with higher scores indicating better practice. Additional parameters assessed included awareness of the Materiovigilance Programme of India, recognition of device malfunction, perception regarding barriers to reporting, and interest in formal training.

Statistical Analysis: The collected data were entered into Microsoft Excel and analyzed using Statistical Package for the Social Sciences (SPSS) version 27.0. Descriptive statistics such as frequency, percentage, mean, and standard deviation were used to summarize participant characteristics and responses. Knowledge, attitude, and practice scores were presented appropriately using tables and summary measures. Associations between categorical variables were analyzed using the Chi-square test or Fisher's exact test wherever applicable. Comparison of mean scores between groups was performed using independent sample t-test or one-way analysis of variance (ANOVA) based on the number of comparison groups and distribution of data. A p-value of less than 0.05 was considered statistically significant.

Results

A total of 200 undergraduate students participated in the study. The sociodemographic profile of the participants is presented in Table 1. The majority of the students belonged to the age group of 20–22 years, accounting for 118 participants (59.00%), followed by 42 participants (21.00%) in the 18–19 years age group and 40 participants (20.00%) in the 23–25 years age group. With regard to gender distribution, female participants were more common, comprising 114 students (57.00%), while male participants constituted 86 students (43.00%). In terms of academic year, the largest proportion of participants were from the final year, with 90 students (45.00%), followed by 62 students (31.00%) from the third year and 48 students (24.00%) from the second year. Regarding course of study, more than half of the participants were MBBS students, totaling 104 (52.00%), whereas 56 students (28.00%) were from nursing and 40 students (20.00%) belonged to allied health sciences.

The knowledge-related responses of the participants regarding materiovigilance are summarized in Table 2. Out of the 200 participants, 126 students (63.00%) had heard about materiovigilance, while 74 students (37.00%) had either not heard about it or did not know about it. A relatively higher level of awareness was observed with respect to the fact that medical devices can cause adverse events, as 154 students (77.00%) answered this correctly, whereas 46 students (23.00%) gave an incorrect response or were unaware. Similarly, 112 participants (56.00%) were able to identify reportable device-related incidents correctly, while 88 participants (44.00%) could not. However, awareness was lower for more specific aspects of materiovigilance. Only 84 students (42.00%) were aware of the Materiovigilance Programme of India (MvPI), compared to 116 students (58.00%) who were not aware. Awareness of designated reporting centers was even lower, with only 68 students (34.00%) responding correctly and 132 students (66.00%) lacking this knowledge. Further, 119 participants (59.50%) knew that students and health professionals can report device-related adverse events, while 81 participants (40.50%) did not know this. The poorest knowledge area was awareness regarding the reporting form or portal for device adverse events, where only 52 students (26.00%) answered correctly and a large majority of 148 students (74.00%) were unaware.

The overall grading of knowledge, attitude, and practice among the participants is shown in Table 3. With respect to knowledge, 46 students (23.00%) had poor knowledge, 108 students (54.00%) had moderate knowledge, and 46 students (23.00%) demonstrated good knowledge. This indicates that more than half of the participants had only a moderate level of understanding regarding materiovigilance, while an equal proportion had either poor or good knowledge. In the attitude domain, the majority of students, 118 (59.00%), exhibited a positive attitude toward materiovigilance, whereas 54 students (27.00%) had a neutral attitude and only 28 students (14.00%) showed a negative attitude. These findings indicate that the perception of materiovigilance among the participants was generally favorable. In contrast, the practice domain revealed less satisfactory findings. More than half of the students, 102 (51.00%), had poor practice, while 70 students (35.00%) had fair practice and only 28 students (14.00%) demonstrated good practice. Thus, although a positive attitude was observed in a majority of participants, this did not translate proportionately into actual reporting-related practice, highlighting a clear gap between awareness or perception and real-world implementation.

The detailed attitude- and practice-related responses are presented in Table 4. A large majority of the participants, 172 students (86.00%), agreed or strongly agreed that materiovigilance is important in patient safety, while only 28 students (14.00%) were neutral or disagreed. Similarly, 164 students (82.00%) agreed or strongly agreed that reporting of device adverse events should be mandatory, whereas 36 students (18.00%) were neutral or disagreed. The strongest positive response was noted for the need for undergraduate training in materiovigilance, where 181 students (90.50%) agreed or strongly agreed, and only 19 students (9.50%) were neutral or disagreed. In addition, 158 students (79.00%) stated that they would be willing to report a device-related adverse event in the future, while 42 students (21.00%) were not willing to do so.

However, the practice-related parameters in the same table revealed considerably lower performance. Only 61 students (30.50%) had ever observed a medical device-related adverse event or problem, while 139 students (69.50%) had not encountered such an event. More importantly, only 18 students (9.00%) had ever reported a device-related adverse event, whereas 182 students (91.00%) had never reported one. Prior training on materiovigilance had been received by only 36 participants (18.00%), while the majority, 164 participants (82.00%), had not received any such training. Familiarity with the reporting form or portal was also low, with only 41 students (20.50%) being familiar with it and 159 students (79.50%) reporting unfamiliarity.

The association between academic year and knowledge level is shown in Table 5. Among second-year students, 18 out of 48 students (37.50%) had poor knowledge, 24 students (50.00%) had moderate knowledge, and only 6 students (12.50%) had good knowledge. Among third-year students, 16 out of 62 students (25.81%)

had poor knowledge, 36 students (58.06%) had moderate knowledge, and 10 students (16.13%) had good knowledge. In contrast, among final-year students, only 12 out of 90 students (13.33%) had poor knowledge, while 48 students (53.33%) had moderate knowledge and as many as 30 students (33.33%) had good knowledge. This distribution demonstrates a progressive improvement in knowledge level with advancement in academic year. The proportion of students with poor knowledge declined from 37.50% in second year to 13.33% in final year, whereas the proportion with good knowledge increased from 12.50% in second year to 33.33% in final year. The association between academic year and knowledge level was found to be statistically significant (Chi-square test, $p = 0.003$), indicating that students in higher academic years had significantly better knowledge regarding materiovigilance compared with those in earlier years.

The association of prior training in materiovigilance with knowledge and practice levels is presented in Table 6. Regarding knowledge level, among the 36 students who had received prior training, only 3 students (8.33%) had poor knowledge, 18 students (50.00%) had moderate knowledge, and 15 students (41.67%) had good knowledge. In comparison, among the 164 students who had not received any training, 43 students (26.22%) had poor knowledge, 90 students (54.88%) had moderate knowledge, and only 31 students (18.90%) had good knowledge. These results indicate that students with prior training had markedly better knowledge levels than those without training. The association between prior training and knowledge level was statistically significant (Chi-square test, $p = 0.007$), showing that formal exposure to materiovigilance training significantly improved student knowledge.

A similar pattern was observed for practice level. Among participants who had received training, 10 students (27.78%) had poor practice, 16 students (44.44%) had fair practice, and 10 students (27.78%) had good practice. On the other hand, among students without prior training, 92 students (56.10%) had poor practice, 54 students (32.93%) had fair practice, and only 18 students (10.98%) had good practice. Therefore, students who had undergone training were much more likely to demonstrate fair to good practice than those who had not received training. This association was highly statistically significant (Chi-square test, $p = 0.001$).

Table 1: Sociodemographic characteristics of study participants (n = 200)

Variable	Category	Frequency (n)	Percentage (%)
Age (years)	18–19	42	21.00
	20–22	118	59.00
	23–25	40	20.00
Gender	Male	86	43.00
	Female	114	57.00
Academic year	Second year	48	24.00
	Third year	62	31.00
	Final year	90	45.00
Course of study	MBBS	104	52.00
	Nursing	56	28.00
	Allied health sciences	40	20.00

Table 2: Distribution of knowledge-related responses on materiovigilance (n = 200)

Knowledge parameter	Correct response	Correct response %	Incorrect/Don't know	Incorrect/Don't know %
Heard about materiovigilance	126	63.00	74	37.00
Aware that medical devices can cause adverse events	154	77.00	46	23.00
Able to identify reportable device-related incidents	112	56.00	88	44.00
Aware of Materiovigilance Programme of India (MvPI)	84	42.00	116	58.00
Aware of designated reporting centers	68	34.00	132	66.00
Knew that students/health professionals can report device-related adverse events	119	59.50	81	40.50
Aware of reporting form/portal for device adverse events	52	26.00	148	74.00

Table 3: Overall knowledge, attitude, and practice grading of participants (n = 200)

Domain	Category	Frequency (n)	Percentage (%)
Knowledge	Poor	46	23.00
	Moderate	108	54.00
	Good	46	23.00
Attitude	Negative	28	14.00
	Neutral	54	27.00
	Positive	118	59.00
Practice	Poor	102	51.00
	Fair	70	35.00
	Good	28	14.00

Table 4. Attitude and practice-related responses of study participants (n = 200)

Parameter	Response category	Frequency (n)	Percentage (%)
Materiovigilance is important in-patient safety	Agree/Strongly agree	172	86.00
	Neutral/Disagree	28	14.00
Reporting of device adverse events should be mandatory	Agree/Strongly agree	164	82.00
	Neutral/Disagree	36	18.00
Undergraduate students should be trained in materiovigilance	Agree/Strongly agree	181	90.50
	Neutral/Disagree	19	9.50
Willing to report a device-related adverse event in future	Yes	158	79.00
	No	42	21.00
Ever observed a medical device-related adverse event/problem	Yes	61	30.50
	No	139	69.50
Ever reported a device-related adverse event	Yes	18	9.00
	No	182	91.00
Received prior training on materiovigilance	Yes	36	18.00
	No	164	82.00
Familiar with reporting form/portal	Yes	41	20.50
	No	159	79.50

A statistically significant association was observed between academic year and knowledge level. Final-year students had a higher proportion of good knowledge compared with second- and third-year students.

Table 5: Association between academic year and knowledge level (Chi-square test) (n = 200)

Academic year	Poor n (%)	Moderate n (%)	Good n (%)	Total	p value
Second year (n = 48)	18 (37.50)	24 (50.00)	6 (12.50)	48	
Third year (n = 62)	16 (25.81)	36 (58.06)	10 (16.13)	62	
Final year (n = 90)	12 (13.33)	48 (53.33)	30 (33.33)	90	**0.003**

Table 6: Association of prior training in materiovigilance with knowledge and practice levels (Chi-square test) (n = 200)

Variable	Category	Poor n (%)	Moderate/Fair n (%)	Good n (%)	Total	p value
Knowledge level	Training received (n = 36)	3 (8.33)	18 (50.00)	15 (41.67)	36	
	No training (n = 164)	43 (26.22)	90 (54.88)	31 (18.90)	164	**0.007**
Practice level	Training received (n = 36)	10 (27.78)	16 (44.44)	10 (27.78)	36	
	No training (n = 164)	92 (56.10)	54 (32.93)	18 (10.98)	164	**0.001**

Discussion

The sociodemographic profile in the present study showed that most participants were aged 20–22 years (59.00%), females constituted 57.00%, and final-year students formed the largest academic subgroup (45.00%). This pattern is broadly comparable to the pharmacy-student study by Dharman et al. (2025), in which most respondents were also young adults and females predominated, accounting for 74.58% of the sample. The female predominance in both studies may reflect the

enrolment pattern of health-science courses, while the higher proportion of final-year students in the present study is relevant because greater clinical exposure may influence awareness of device-related safety issues. [7]

In the present study, 63.00% of students had heard about materiovigilance and 77.00% were aware that medical devices can cause adverse events. This awareness is lower than that reported by Meher et al. (2022), where 92.63% of medical professionals believed that medical devices can cause adverse events. The difference is understandable because Meher et al. studied faculty and residents who were already engaged in clinical practice, whereas the present study involved undergraduates whose exposure to reporting systems and device surveillance is still evolving. Even so, the finding that nearly one-fourth of the present participants were unaware that devices can cause adverse events indicates an important educational gap at the undergraduate level. [8]

The more specific knowledge components in the present study were clearly weaker than the basic conceptual awareness. Only 42.00% of participants knew about the Materiovigilance Programme of India, 34.00% were aware of designated reporting centers, and just 26.00% knew about the reporting form or portal. Comparable deficiencies were also observed by Panchal et al. (2022) among medical surgeons in Gujarat, where only 31.40% were aware of India's current materiovigilance program, although 71.80% had some idea about the various reporting systems in India. Compared with that study, awareness of the national program in the present study was slightly higher, but procedural knowledge regarding where and how to report remained poor, reinforcing that undergraduate students may recognize the concept of device harm without understanding the operational steps of reporting. [9]

When the overall grading was considered, 54.00% of the present participants had moderate knowledge, 59.00% had a positive attitude, but 51.00% had poor practice. This "better attitude than practice" pattern is similar to that described by Upadhyaya et al. (2015) among postgraduate students, where the average correct knowledge was only 34.83%, yet 90.76% agreed that ADR reporting was necessary, mandatory, and beneficial for patient safety, while only 7.92% had actually reported an ADR. Although that study dealt with pharmacovigilance rather than materiovigilance, the same behavioral gap is evident: favorable perception alone does not ensure reporting behavior unless students are trained in the reporting process and are given practical exposure. [10]

The attitude findings of the present study were notably encouraging. A large majority agreed that materiovigilance is important for patient safety (86.00%), that reporting should be mandatory (82.00%), and that undergraduate students should be trained in materiovigilance (90.50%); moreover, 79.00% stated willingness to report a device-related adverse event in the future. These findings closely parallel those of Marko et al. (2019), who reported that 83.33% of medical students considered ADR reporting necessary and 91.66% felt pharmacovigilance should be taught to all healthcare professionals. The consistency between the two studies suggests that healthcare students generally possess a favorable attitude toward safety reporting, and that the main problem lies less in motivation and more in inadequate curricular reinforcement and reporting skills. [11]

Despite this positive attitude, the practice indicators in the present study remained unsatisfactory. Only 30.50% of participants had ever observed a device-related adverse event, only 9.00% had ever reported one, only 18.00% had received prior training, and just 20.50% were familiar with the reporting form or portal. A similar trend was reported by Saranraj et al. (2024), where 63.30% of doctors and postgraduate residents had encountered medical device-related adverse events in practice, yet only 12.10% had reported them, although 93.50% were willing to report in future. Compared with that study, the present undergraduates had fewer opportunities to encounter events, but once again the conversion of awareness into actual reporting was weak, indicating that underreporting is already established at the training stage and not only after entering professional practice. [12]

A significant association was observed in the present study between academic year and knowledge level ($p = 0.003$), with good knowledge increasing from 12.50% in second-year students to 33.33% in final-year students. This progressive improvement is in agreement with the postgraduate study by Polillan et al. (2025), in which 55.41% of postgraduates had adequate knowledge and 59.46% had a positive attitude toward materiovigilance. Although the study populations are not identical, both findings support the view that advancing academic seniority and clinical responsibility are associated with better understanding of safety monitoring systems. This likely reflects cumulative exposure to devices, patient care, and departmental teaching during later stages of training. [13]

An important strength of the present study is that it demonstrated a statistically significant relationship between prior training and both knowledge ($p = 0.007$) and practice ($p = 0.001$). Among students who had received training, 41.67% had good knowledge compared with only 18.90% among untrained students, and 27.78% showed good practice compared with 10.98% among those without training. This observation is strongly

supported by Thakare et al. (2025), who showed that sensitization significantly improved pharmacovigilance knowledge among students, including ADR reporting knowledge (82.50% vs 62.80% between medical and paramedical groups at baseline, with significant post-intervention gains in reporting-form awareness). Their findings, like ours, suggest that structured educational interventions can directly improve reporting literacy and should be integrated formally into undergraduate teaching. [14]

Overall, the present study demonstrates that undergraduate students possess moderate knowledge and favorable attitudes toward materiovigilance, but their actual reporting behavior is poor because of limited procedural awareness and insufficient training. This interpretation is further supported by Yadav et al. (2024), who found among oral health practitioners that only 12.10% reported adverse events, only 9.50% had attended training in the previous year, and 79.50% did not report because they did not know how or where to report. The similarity between that study and the present findings suggests that the central barrier is not unwillingness but lack of training, reporting familiarity, and system orientation. Therefore, undergraduate curricula should include formal materiovigilance teaching, demonstration of reporting forms and portals, and practical sensitization sessions so that positive attitudes can translate into competent reporting practice. [15]

Conclusion

This study concludes that undergraduate students at a tertiary care hospital had moderate knowledge and a generally positive attitude toward materiovigilance, but their actual reporting practice was poor. Awareness of the concept was better than familiarity with reporting procedures, forms, and reporting centers. Academic seniority and prior training were significantly associated with better knowledge and practice, highlighting the importance of structured teaching. Integrating formal materiovigilance training, practical demonstrations, and sensitization sessions into undergraduate education may help translate positive attitudes into effective reporting behavior.

References

1. World Health Organization. Global patient safety action plan 2021-2030: towards eliminating avoidable harm in health care. Geneva: World Health Organization; 2021. Available from: https://www.who.int/publications/i/item/9789240032705
2. Indian Pharmacopoeia Commission. Guidance document: Materiovigilance Programme of India (version 1.2) [Internet]. Ghaziabad: Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India; 2020. Available from: https://www.ipc.gov.in/images/Guidance_Document_MvPI.pdf
3. Date AP, Date AA, Siddiqui RA, Shende TR, Salankar HV, Quazi SH, et al. Materiovigilance programme of India: a step towards patient safety. Int J Basic Clin Pharmacol. 2023;12(4):621-625. doi:10.18203/2319-2003.ijbcp20231902. Available from: https://www.ijbcp.com/index.php/ijbcp/article/view/5312
4. Sun J, Pan J, Jin Y, Zhang Q, Lv Y, Feng J. Establishment of a medical device adverse event management system for hospitals. BMC Health Serv Res. 2022;22(1):1406. doi:10.1186/s12913-022-08830-5. Available from: https://pmc.ncbi.nlm.nih.gov/articles/PMC9685867/
5. Alsohime F, Temsah MH, Hasan G, Al-Eyadhy A, Gulman S, Issa H, et al. Reporting adverse events related to medical devices: a single center experience from a tertiary academic hospital. PLoS One. 2019;14(10):e0224233. doi:10.1371/journal.pone.0224233. Available from: https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0224233
6. Mishali M, Sheffer N, Negev M. Challenges and dynamics in reporting medical device incidents: a qualitative study. Front Health Serv. 2025;5:1720494. doi:10.3389/frhs.2025.1720494. Available from: https://www.frontiersin.org/journals/health-services/articles/10.3389/frhs.2025.1720494/full
7. Dharman D, Prasanth LM, Mohan NP, Vijayan S. Assessing knowledge, attitude and practice of materiovigilance among pharmacy students in South Kerala: a cross-sectional study. Indian J Pharm Pract. 2025;18(3):308-314. doi:10.5530/ijopp.20250226.
8. Meher BR, Padhy BM, Srinivasan A, Mohanty RR. Awareness, attitude, and practice of materiovigilance among medical professionals at a tertiary care institute of national importance: a cross-sectional study. Perspect Clin Res. 2022;13(2):94-98.
9. Panchal YN, Vyas BM, Suthar KM, Shah KN. A study of assessing knowledge, attitude, and practice of materiovigilance among medical surgeons of Gujarat. Natl J Physiol Pharm Pharmacol. 2022;12(11):1792-1797. doi:10.5455/njppp.2022.12.03103202207032022.
10. Upadhyaya HB, Vora MB, Nagar JG, 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;6(1):29-34. doi:10.4103/2231-4040.150369.
11. Marko S. A study of knowledge, attitude, and practice of pharmacovigilance among medical students at a tertiary care teaching hospital in Madhya Pradesh, India. Natl J Physiol Pharm Pharmacol. 2019;9(9):851-855. doi:10.5455/njppp.2019.9.0620408062019.
12. Saranraj K, Usha Kiran P. A study assessing the knowledge, attitude, and practice of materiovigilance among medical professionals in the states of Tamil Nadu and Andhra Pradesh, India. Int J Basic Clin Pharmacol. 2024;13(3):364-370. doi:10.18203/2319-2003.ijbcp20240993.
13. Polillan GR, Prathap B, Viswasrao SM. Knowledge, attitude, and practice of materiovigilance among postgraduate students at a tertiary care hospital: a cross-sectional observational study. Educ Med. 2025;26(1):100973. doi:10.1016/j.edumed.2024.100973.
14. Thakare V, Jain M, Reza M, Patil A, Langade D. Impact of pharmacovigilance sensitization on knowledge and attitude amongst medical and paramedical students in a tertiary care teaching hospital: a questionnaire-based study. Cureus. 2025;17(10):e94002. doi:10.7759/cureus.94002.
15. Yadav L, Mehra P, Vasisth D, Mattu N, Biswas K, Yadav N. Assessment of knowledge, attitude, and practice of pharmacovigilance and materiovigilance among oral health practitioners in India. J Pharm Bioallied Sci. 2024;16(Suppl 1):S202-S205. doi:10.4103/jpbs.jpbs_456_23.