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ORIGINAL RESEARCH ARTICLE

Assessing the Knowledge, Attitude, and Practice of Materiovigilance among the Faculty and Residents of a Tertiary Care Hospital –A Mixed method study

Dr. Munirajulu Rajanikanth[1], Dr. Altaf Hussain Shaik[2], Dr. Bogarrapu Durga Monica[3]*

[1]Associate Professor, Department of Pharmacology, Kurnool Medical College, Kurnool, Andhra Pradesh
[2]Assistant Professor, Department of Pharmacology, Kurnool Medical College, Kurnool, Andhra Pradesh
[3]Assistant Professor, Department of Pharmacology, Santhiram Medical College, Nandyala, Andhra Pradesh

Corresponding Author: Dr. Bogarrapu Durga Monica
Email: monica28boggarapu@gmail.com

Abstract: Background:Materiovigilance is essential for monitoring medical device-associated adverse events and ensuring patient safety.Aim: To assess the knowledge, attitude, and practice of materiovigilance among faculty and postgraduate residents. Materials and Methods: A mixed-methods study was conducted over three months at a tertiary care hospital in Kurnool, Andhra Pradesh. A total of 210 faculty members and postgraduate residents from various departments were recruited using convenience sampling. Quantitative data were collected using a structured, self-administered, English-language questionnaire comprising nine knowledge questions, nine attitude items, and five practice questions. Knowledge, attitude, and practice scores were analyzed descriptively using frequencies and percentages. Qualitative data were obtained through focused group discussions among participants with poor knowledge scores and analyzed thematically. Results: The overall knowledge, attitude, and practice scores were 72.6%, 93.6%, and 69.1%, respectively. All participants routinely checked device functionality, but only 48.1% had received formal reporting training. Key barriers included inadequate awareness, workload, limited reporting access, and fear of administrative consequences.Conclusion: Despite a highly positive attitude, gaps in knowledge and practice highlight the need for regular training, simplified reporting procedures, and institutional support to improve materiovigilance.

Keywords: Materiovigilance, medical devices, patient safety, Healthcare Professionals Materiovigilance Programme of India

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Introduction

Materiovigilance(Mv) envisages close monitoring of any undesirable performance or characteristics fluctuations of a medical device by means of a system which can identify, collecting, reporting with estimate of undesirable occurrences and reacting to them with field safety corrective actions or device recall during post -marketing phase of a medical device [1]**.** TheMateriovigilance Program of India(MvPI) is part of a broader initiative to integrate materiovigilance into the existing pharmacovigilance framework, thereby ensuring comprehensive safety monitoring across pharmaceuticals and medical devices.[2] Medical devices are widely used to diagnose, prevent, and treat different diseases [3] and range from simple meter dose inhalers to complicated operation theater and radiology devices. Hence, with each new product being launched into the market, practitioners, policymakers, regulators, and patients must become aware of their safety, effectiveness, quality assurance, and other essential parameters,

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which long-term pharmacovigilance (Pv) activities can explore. A similar concept and approach of Pv have been incorporated in medical devices, termed materiovigilance (Mv) [4]**.** Although medical devices benefit the patients by facilitating diagnosis and management, the use of it is not entirely risk-free. Many times, medical devices use has caused morbidity and mortality in device users.[5] In the past, some devices such as breast implants, pacemakers, and hips prosthesis were recalled due to malfunction. [6,7]. It becomes essential to assess the risks and benefits during the premarketing development of the device as well as during its use through a robust-reporting mechanism .MvPI is launched in India on July 6, 2015 to create the awareness among the health care professionals about the importance of medical device-associated adverse events (MDAE) reporting and generate independent credible evidence-based safety data of medical devices.[1,3] Although the program is launched nearly 10 years ago and fewer articles were found published from Andhra Pradesh which made us to undertaken research on materiovigilance in terms of knowledge, attitude and practice which made us to undertake this study.

Aim

To assess the knowledge, attitude and practice of faculty and residents on materiovigilance in a tertiary care hospital.

Objective

1. To identify areas where knowledge gaps, negative attitudes, or inadequate practices exist.
2. To recommend strategies to improve awareness, reporting rates, and integration of materiovigilance into routine clinical practice.

Methods and materials

The study was conducted over a period of three months at a tertiary care hospital in Kurnool using mixed-methods, questionnaire-based study design. The study population comprised medical faculty and postgraduate residents from all departments who were willing to provide informed consent. Interns, undergraduate students, and healthcare professionals who were on long leave or unavailable during data collection were excluded. Convenience sampling was used to recruit participants based on accessibility and willingness to participate. The sample size was calculated using the formula \(n = Z^2pq/e^2\), considering a prevalence of 50%, a 95% confidence interval, and a 7% margin of error. The calculated sample size was 196, which was increased to 210 after accounting for a 10% allowance for non-response or missing data.

Study tool

A structured, self-administered Google form-based questionnaire in the English language was prepared inspired by previous KAP studies [8**,**9,10] and articles on materiovigilance [1-4] to collect the relevant data of the study variables for Quantitative study component. The questionnaire has 4 sections, among which 1st is for collecting details of participants and consent. The remaining 3 sections comprise of 23-item questionnaire to assess the knowledge of materiovigilance, attitude toward MDAE reporting, and practice of materiovigilance. The "knowledge" section consists of nine closed-ended questions. A score of 0 and 1 is given for each wrong and correct response, respectively, and total knowledge score for each participant varies from 0 to 9 and knowledge will be assessed on Bloom's knowledge score categorized as Good (80–100%), Moderate (60–79%), and Poor (<60%).Three-point Likert scale type of questions is included in "attitude" section and a score of 3, 2, and 1is given for each question with agree, neutral, and disagree responses, respectively for questions 1-7 and negative three-point Likert scale type for 8th and 9th questions and a score of 1,2, and 3 is given for each question with agree, neutral, and disagree responses, respectively .Participants with a total attitude score of 75% of maximum score is considered to have a positive attitude toward MDAE reporting. The "practice" section consists of closed-ended questions with dichotomous (yes/no) responses. For qualitative component, Focused group discussions on perceptions and opinions for 15-20 mins was conducted among 6-10 participants. These participants were randomly selected from the participants who scored less than 60% in the knowledge section. This data was transcribed, subjected to thematic analysis to recommend strategies to improve awareness, reporting rates, and integration of materiovigilance into routine clinical practice. The study was conducted after the approval of the Institutional Ethics Committee.

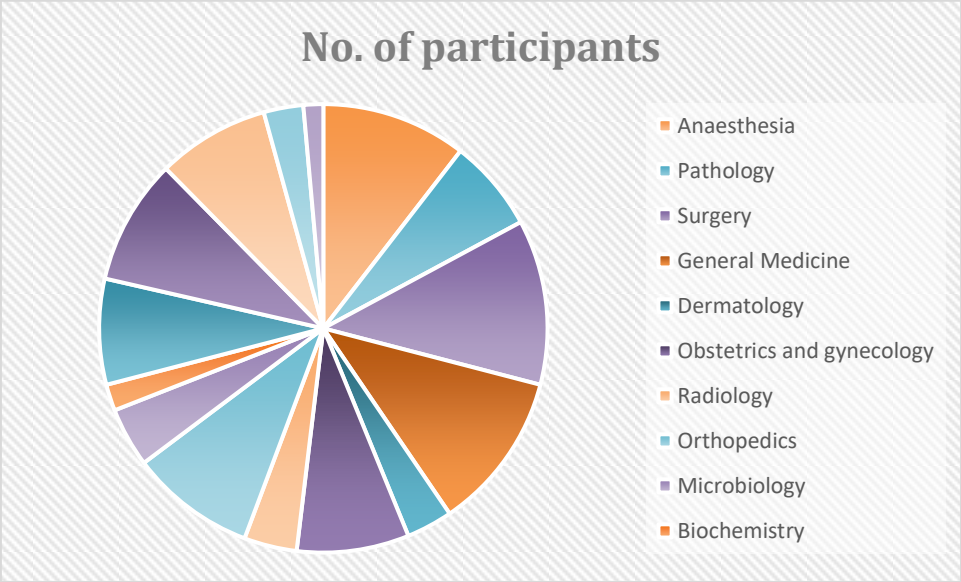
Data Analysis: Data was collected in Microsoft excel 2024 and analyzed by SPSS version 28. Data is presented as frequencies and percentage for Quantitative analysis. Thematic analysis was done for qualitative data.

Results

Demographic details

A total of 210 participants were included in the study, comprising 82 (39.1%) faculty members and 128 (60.9%) postgraduate students.

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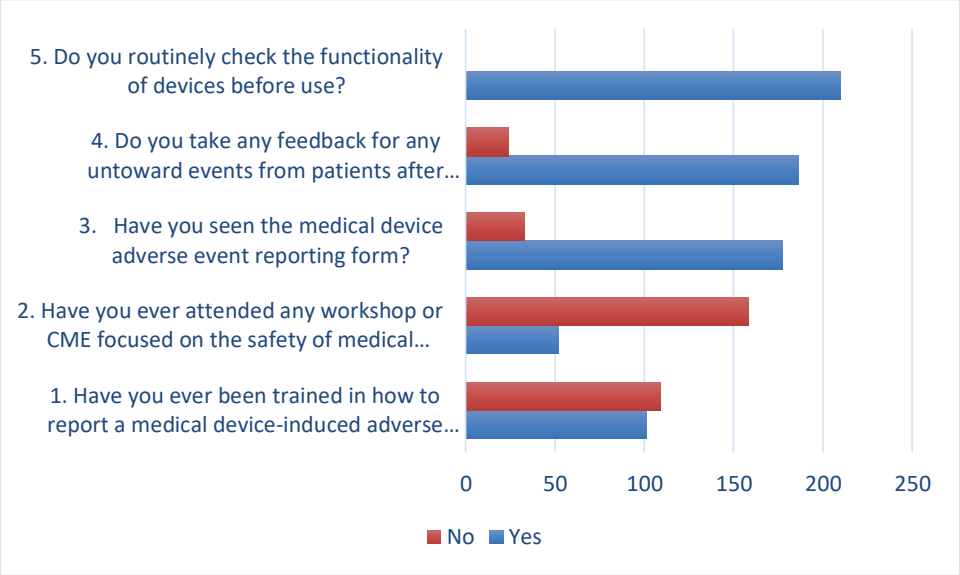
A total of 210 participants were included in the study. The highest number of participants were from the Department of Surgery (25, 11.9%), followed by General Medicine (24, 11.4%), Anesthesia (22, 10.5%), Orthopedics and Ophthalmology (19 each, 9.0%), Pharmacology and Obstetrics & Gynecology (17 each, 8.1%), ENT (16, 7.6%), Pathology (14, 6.7%), Microbiology (9, 4.3%), Radiology (8, 3.8%), Dermatology (7, 3.3%), Respiratory Medicine (6, 2.9%), Biochemistry (4, 1.9%), and Physiology (3, 1.4%).

Questions for Knowledge	Correct responses
1. Which is the program initiated in INDIA for monitoring adverse events due to medical devices?	199
2. Which tool can you use for reporting adverse events caused by medical devices?	202
3. Medical devices are divided into A, B, C, D Categories based on?	117
4. Who can report medical devices induced adverse events?	208
5.Which of the following is a class A type of medical device according to CDSCO medical devices classification?	85
6. Which of the following adverse events need not to be reported?	133
7.What does the term MDAE stand for?	108
8.What should be reported in materiovigilance?	176
Are all partnering organizations of MvPI except?	144

Attitude	Responses		
	Agree	Neutral	Disagree
1. Do you agree medical devices can cause an adverse event?	167	28	15
2. Do you think it is a medical professional's responsibility to report every medical device-induced adverse event?	188	20	2
3. Do you think medical device-induced adverse event reporting should be compulsory?	171	27	12
4.Do you think training on materiovigilance should be a mandatory part of medical education and hospital orientation?	200	7	3
5. Are you willing to report a medical device-induced adverse event?	144	59	7
6. Reporting medical device-related adverse events (MDAEs) helps in improving the overall quality of healthcare.	169	36	5
7. I feel that materiovigilance is as important as pharmacovigilance in patient safety.	200	20	0
8. Do you feel that most healthcare professionals are unaware of the Materiovigilance Program of India (MvPI).	10	8	192
9.Do you feel concerned that reporting MDAEs might lead to legal or administrative consequences.	6	49	155

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Questions for practice	Yes	No
1. Have you ever been trained in how to report a medical device-induced adverse event?	101	109
2. Have you ever attended any workshop or CME focused on the safety of medical devices?	52	158
3 Have you seen the medical device adverse event reporting form?	177	33
4. Do you take any feedback for any untoward events from patients after implanting the device?	186	24
5.Do you routinely check the functionality of devices before use?	210	0



The overall knowledge score, calculated using Bloom's cut-off criteria, was **72.6% (1372/1890)**, indicating **moderate knowledge** regarding materiovigilance and medical device adverse event reporting. The overall attitude score, calculated using a three-point Likert scale (Agree = 3, Neutral = 2, Disagree = 1, with reverse scoring for negatively worded statements), was **5306/5670 (93.6%)**, corresponding to a mean attitude score of **25.27 out of 27**, reflecting a **highly positive attitude** toward materiovigilance. The overall practice score was **726/1050 (69.1%)**, indicating **moderate practice** related to medical device adverse event reporting. Although all participants routinely checked the functionality of medical devices before use (100%), fewer participants had received formal training in reporting medical device-induced adverse events (48.1%) or attended workshops/CME on medical device safety (24.8%).

Thematic Analysis of Focus Group Discussion

The thematic analysis of the focus group discussion identified three major themes:

Theme	Key findings
Knowledge and awareness gaps	Participants reported limited awareness of the Materiovigilance Programme of India (MvPI), inadequate knowledge of reporting procedures, and lack of formal training on medical device adverse event reporting.
Barriers to reporting	Major barriers included heavy workload, uncertainty regarding reportable events, limited access to reporting forms, and concerns about legal or administrative consequences.
Strategies to improve reporting	Participants recommended regular CMEs and workshops, incorporation of materiovigilance into the medical curriculum, simplified reporting procedures, easy availability of reporting forms, and greater institutional support to improve reporting practices.

The focused group discussion among participants with poor knowledge (Bloom's score <60%) and low attitude scores revealed that inadequate awareness, lack of formal training, misconceptions regarding reporting, and operational barriers were the primary reasons for poor knowledge and unfavorable attitudes toward materiovigilance.

The findings of the present study were compared with previously published studies on knowledge, attitude, and practice (KAP) regarding materiovigilance among healthcare professionals.

Sivagourounadin et al. [8] (2022) conducted a cross-sectional study among 400 nurses at a tertiary care hospital in South India. They reported adequate knowledge in 65.7% of participants and a positive attitude toward medical device-associated adverse event (MDAE) reporting in 80.5%. However, only 4.5% had reported an MDAE. In comparison, the present study found an overall knowledge score of 72.6% and a highly positive attitude score of 93.6%. Similarly, the present study identified gaps in formal training, with only 48.1% of participants having received training in adverse event reporting. Although the practice measures and scoring methods differed between the studies, both highlight the need to improve the translation of knowledge and positive attitudes into effective reporting practices.

Saranraj and Kiran [9] (2024) assessed materiovigilance among medical professionals in Andhra Pradesh and Tamil Nadu. Among 496 respondents, 96.8% recognized that medical devices could cause adverse events, and 91.1% agreed that healthcare professionals were responsible for reporting them. Despite 63.3% reporting experience with device-related adverse events, only 12.1% had actually reported such events, although 93.5% expressed willingness to report.In the present study, 79.5% agreed that medical devices could cause adverse events, and 89.5% considered reporting a professional responsibility. These findings indicate a similarly favorable perception of the importance of reporting, although the proportions differed. The present study also found that only 68.6% expressed willingness to report, suggesting a potential gap between recognizing the importance of materiovigilance and willingness to participate in reporting. Differences in study populations, questionnaires, and scoring methods should be considered when interpreting these findings.

Kulkarni et al. [10] (2025) studied 73 postgraduate students at a tertiary care institute and reported adequate knowledge in 55.41%, a positive attitude in 59.46%, and good practice in 77.03%. Compared with their findings, the present study showed a higher overall knowledge score and a more favorable attitude. However, the present study's overall practice score was 69.1%, indicating moderate practice, whereas Kulkarni et al. reported good practice among a majority of participants. These differences may reflect variation in participant characteristics, questionnaire design, scoring criteria, and institutional practices.

Study on the impact of sensitization on materiovigilance among pharmacy and dental postgraduate students (2024) reported that 64.8% of participants were unaware of MvPI, 97.5% had a positive attitude toward reporting MDAEs, only 5% had received reporting training, and 85.71% had never seen the reporting form. n comparison, the present study demonstrated greater familiarity with basic reporting mechanisms: 96.2% correctly identified the reporting tools, and 84.3% had seen the reporting form. Nevertheless, formal training remained insufficient, with fewer than half of the participants trained. Both studies reinforce the importance of structured educational interventions and practical training in medical device safety.

Taken together, the available studies suggest that positive attitudes toward materiovigilance are relatively common, while knowledge of specific reporting procedures, formal training, and actual reporting behavior remain important areas for improvement. The present study adds to this evidence by examining both faculty members and postgraduate residents across multiple departments in a tertiary care hospital. Its mixed methods design also identifies institutional barriers, including workload, uncertainty about reportable events, limited access to reporting forms, and concerns about administrative consequences.

Therefore, the findings support implementing regular CMEs, simplified reporting procedures, readily accessible reporting forms, and institutional support to improve materiovigilance practices. Direct numerical comparisons should be interpreted cautiously because the studies used different populations, questionnaires, and scoring systems.

Limitations

The study was conducted at a single centre using convenience sampling and self-reported data, which may limit generalizability and introduce bias. The cross-sectional design and focused group discussions involving selected participants may limit causal interpretation and the diversity of perspectives.

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Conclusion

The study revealed moderate knowledge and practice but a highly positive attitude toward materiovigilance among faculty members and postgraduate residents. Inadequate formal training and institutional barriers remain important challenges. Regular CMEs, practical training, accessible reporting forms, simplified reporting procedures, and integration of materiovigilance into medical education are recommended to strengthen medical device adverse-event reporting and improve patient safety.

Conflict of interest – Nil

Acknowledgements - We express our gratitude to the faculty members and postgraduate residents for their valuable participation and cooperation.

Google form questionnaire

KNOWLEDGE

1. Which is the program initiated in INDIA for monitoring adverse events due to medical devices?

- ❑ Pharmacovigilance
- ❑ **Materiovigilance**
- ❑ Adverse Events Following Immunization
- ❑ Hemovigilance

2. Which tool can you use for reporting adverse events caused by medical devices?

- ❑ helpline number – 18001803024
- ❑ mvpi.ipcindia@gmail.com
- ❑ Customized MDAE reporting form submitted to MDMC
- ❑ **all the above**

3. Medical devices are divided into A, B, C, D Categories based on?

- ❑ Their prices
- ❑ **the risk they carry**
- ❑ their use in different diseases
- ❑ their complexity of structure

4. Who can report medical devices induced adverse events?

- ❑ Doctors
- ❑ Patients
- ❑ biomedical engineers
- ❑ **All the above**

5.Which of the following is a class A type of medical device according to CDSCO medical devices classification?

- ❑ **surgical dressings**
- ❑ disposable needle
- ❑ intraocular lens
- ❑ drug eluting stents

6. Which of the following adverse events need not to be reported?

- ❑ death of the patient due to fire in incubator
- ❑ Surgical gloves causing irritation of the skin
- ❑ infusion pump fails to give an appropriate alarm
- ❑ **none of the above**

7.What does the term MDAE stand for?

- ❑ Medical Drug Adverse Event
- ❑ Medical Device Adverse Effect
- ❑ **Medical Device-Associated Adverse Event**
- ❑ Medical Diagnostic Associated Error

8.What should be reported in materiovigilance?

- ❑ Serious adverse events due to medical devices.
- ❑ Unknown adverse events due to medical devices.
- ❑ rare adverse events due to medical devices.
- ❑ **All the above**

9. Are all partnering organizations of MvPI except?

- ❑ Central Drugs Standard Control Organisation (CDSCO) New Delhi
- ❑ **United Nations International Children's Emergency Fund (UNICEF)***
- ❑ Sri Chitra Tirunal Institute of Medical Science & Technology (SCTIMST)
- ❑ Indian Pharmacopoeia Commission

ATTITUDE

1. Do you agree medical devices can cause an adverse event?

A) AGREE B) NEUTRAL**C)** DISAGREE

2. Do you think it is a medical professional's responsibility to report every medical device-induced adverse event?

A) AGREE **B)** NEUTRAL**C)** DISAGREE

3. Do you think medical device-induced adverse event reporting should be compulsory?

A) AGREE **B)** NEUTRAL**C)** DISAGREE

4. Do you think training on materiovigilance should be a mandatory part of medical education and hospital orientation?

A) AGREE **B)** NEUTRAL **C)** DISAGREE

5. Are you willing to report a medical device-induced adverse event?

A) AGREE **B)** NEUTRAL**C)** DISAGREE

6. Reporting medical device-related adverse events (MDAEs) helps in improving the overall quality of healthcare.

A) AGREE **B)** NEUTRAL **C)** DISAGREE

7. I feel that materiovigilance is as important as pharmacovigilance in patient safety.

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A) AGREE **B)** NEUTRAL
C) DISAGREE

8. Do you feel that most healthcare professionals are unaware of the Materiovigilance Program of India (MvPI).

A) AGREE **B)** NEUTRAL
C) DISAGREE

9.Do you feel concerned that reporting MDAEs might lead to legal or administrative consequences.

A) AGREE **B)** NEUTRAL
C) DISAGREE

PRACTICE

1. Have you ever been trained on how to report a medical device-induced adverse event?

- ❑ Yes
- ❑ No

2. Have you ever attended any workshop or CME focused on the safety of medical devices?

- ❑ Yes
- ❑ No

3. Have you seen the medical device adverse event reporting form?

- ❑ Yes
- ❑ No

4. Do you take any feedback for any untoward events from patients after implanting the device?

- ❑ Yes
- ❑ No

5.Do you routinely check the functionality of devices before use?

- ❑ Yes
- ❑ No

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