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Original Article

Materiovigilance in surgical care: A cross-sectional KAP study among surgeons.

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Abstract

Background:

Surgical devices and instruments play a vital role in patient safety and clinical outcomes. Materiovigilance, the systematic monitoring of adverse events and risks associated with medical devices, is essential in ensuring safer surgical practice.

Objective:

To assess the knowledge, attitudes, and practices (KAP) of surgeons regarding materiovigilance in surgical care.

Methods:

A cross-sectional, questionnaire-based study was conducted among practicing surgeons from various specialties in Navi Mumbai. The survey explored knowledge of materiovigilance, reporting practices, barriers to reporting, and attitudes towards medical device safety.

Results:

A total of 149 surgeons participated. About 67.8% correctly identified India's Materiovigilance Programme (MvPI), and 75.2% were aware that all healthcare professionals can report device-related adverse events. While 69.1% acknowledged that surgical devices may cause adverse events, 85.2% felt reporting was a surgeon's responsibility, and 80.5% supported making it mandatory. Nearly half (48.3%) had encountered a device-related adverse event, but only 25.5% reported it. Notably, 80.5% had never received formal training on adverse event reporting.

Conclusion:

Awareness regarding materiovigilance among surgeons was suboptimal. Strengthening training, creating user-friendly reporting platforms, and integrating materiovigilance into surgical practice are crucial for improving patient safety.

Recommendation:

Regular training programs on materiovigilance, simplified and accessible reporting systems, and mandatory integration of device safety reporting into routine surgical practice are recommended to enhance reporting compliance and patient safety.

Keywords: *Materiovigilance, Surgical devices, Patient safety, Surgeons, India.*
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Introduction

Medical devices play a vital role in the diagnosis, monitoring, and management of diseases.[1] A medical device is defined as any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material, or other similar or related article intended for the diagnosis, prevention, treatment, or alleviation of disease.[2] Devices can range from simple tools such as cotton bandages and syringes to advanced technologies like heart pacemakers, coronary stents, imaging systems, and even digital applications.[3] Medical devices have played the most important role in patient care. The World Health Organization has advocated an essential diagnostics list, similar to the essential medicines list, in recognition of the growing relevance of medical devices in health-care delivery.[4]

In surgical care, devices and instruments—including laparoscopes, cautery machines, staplers, suture materials, and endoscopes—are indispensable. While they improve precision and patient outcomes, they also pose risks such as mechanical failure, malfunction, or device-related adverse events.[5] Unlike drugs, where Pharmacovigilance is well-established, the concept of materiovigilance—systematic monitoring and reporting of adverse events associated with medical devices—is relatively new.

The Materiovigilance Programme of India (MvPI) was launched on July 6, 2015, by the Drug Controller General of India, Dr. G.N. Singh, at the Indian Pharmacopoeia Commission, Ghaziabad. The initiative aims to sensitize healthcare professionals to the importance of reporting medical device–associated adverse events and to generate independent, reliable, and evidence-based data on medical device safety.[6] The Materiovigilance Programme of India aims to monitor medical device–associated adverse events (MDAEs) and raise awareness among surgeons about the importance of reporting such events. The programme also evaluates the benefit–risk profile of medical devices used in surgical practice. Dedicated Medical Device Adverse Event Monitoring Centers have been established across the country to ensure systematic safety surveillance. It is crucial for surgeons to be familiar with materiovigilance principles to enhance patient safety, prevent device-related complications, and provide optimal surgical outcomes.[7]

However, awareness and reporting practices among healthcare professionals, especially surgeons, remain limited. Since surgeons are among the most frequent users of medical devices, their perspectives are crucial for strengthening materiovigilance in surgical care. This study was designed to evaluate the awareness and perspectives of surgeons towards materiovigilance, identify barriers to reporting, and suggest strategies for improving safe surgical practice.

Methodology

This was an observational, cross-sectional, and questionnaire-based (KAP) study, conducted among practicing medical surgeons of Navi Mumbai, India. The study was conducted over 3 months from February 2025 to April 2025, following approval from the D Y Patil Institutional Ethics Committee (IEC BH reference No.: 2023/113) dated 13-05-2024.

The sample size was calculated using the formula $n = Z^2 \times p(1-p) / d^2$, assuming a 50% expected awareness rate (p = 0.5) to achieve maximum sample size with a 95% confidence level (Z = 1.96) and 8% margin of error (d = 0.08). The calculated minimum sample size was 150 participants. A total of 149 surgeons completed the survey.

To minimize bias, voluntary participation was ensured, and the questionnaire was kept anonymous to reduce social desirability bias. Selection bias was minimized by distributing the hard copy of the questionnaire across multiple surgical specialties during outpatient department (OPD) sessions. Response bias was addressed by using closed-ended, structured questions to standardize data collection and interpretation.

The final questionnaire comprised 18 questions, organized into three sections: Section A for demographic details (3 questions), Section B for knowledge regarding materiovigilance (7 questions), and Section C for perspectives, including attitudes (5 questions) and practices (3 questions) related to materiovigilance in surgical care.

Knowledge of the study participants was assessed using a scoring system, with a score of "1" assigned for each correct response and "0" for each incorrect response. Attitudes toward materiovigilance in surgical care were evaluated through five attitude-related questions, of which two were closed-ended ("Yes" or "No") and three were based on a 4-point Likert scale with options: "Strongly agree," "Agree," "Disagree," and "Strongly disagree." Practice related to materiovigilance was assessed through three closed-ended ("Yes" or "No") questions. The questionnaire was shared with participants via a secure online link circulated through social media and messaging platforms, and responses were collected digitally.

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Inclusion criteria

- Practicing surgeons from various surgical specialties who were willing to participate.

Exclusion criteria

- Individuals unwilling to provide informed consent to participate in the study.
- Medical professionals who are not involved in surgical practice (e.g., non-surgeon consultants, non-surgical residents).

Statistical analysis:

All data were entered in Microsoft Excel and analyzed using the Statistical Package for the Social Sciences (SPSS), version 20.0. Categorical variables were presented as frequencies and percentages, while continuous variables were summarized as mean ± standard deviation (SD). Comparisons between two groups for continuous variables were performed using the independent samples t-test.

Results:

We received a total of 149 responses during the study period. Out of 149 participants, 119 (79.86%) were male, while 30 (20.13%) were female. [Table 1].

Table 1: Demographic characteristics of study participants (n=149).

Demographic characteristics	Categories	Frequency (%)
Age (years)	≤ 30	10 (6.71)
	31-40	23 (15.43)
	41-50	54(36.24)
	51-60	33 (22.14)
	> 60	29 (19.46)
Gender	Male	119 (79.86)
	Female	30 (20.13)
Field of Surgery	M.S. General Surgery	53 (35.57)
	M.S. Orthopedics	31 (20.80)
	M.S. ENT	17 (11.40)
	M.S. Opthalmology	19 (12.75)
	M.D. Obstetrics and Gynecology	24 (16.10)
	M.Ch. Urology	3 (2.01)
	M.Ch. Surgical oncology	2 (1.34)

Table 1 represents: Most participants were middle-aged surgeons, predominantly male, with nearly half aged 41–50 years. General Surgery and Orthopedics were the most represented specialties, while Urology and Surgical Oncology had the fewest participants.

Table 2: Knowledge of study participants regarding materiovigilance (*n*=149).

Knowledge Assessment Questions	Correct Response	Incorrect Response
	n(%)	n (%)
1. On which basis are medical devices classified A, B, C, and D in India?	92 (61.7)	57(38.3)
2. Which of the following medical devices belongs to Category A?	74 (49.7)	75 (50.3)
3. What is the name of India's program for monitoring adverse events related to medical	101 (67.8)	48 (32.2)

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devices?		
4. Who is eligible to report a medical device-related adverse event (MDAE)?	112 (75.2)	37 (24.8)
5. Which organization acts as the National Coordination Centre for MvPI?	85 (57.0)	64 (43.0)
6. Which of the following events need NOT be reported under materiovigilance?	69 (46.3)	80 (53.7)
7. What reporting systems are available in India for MDAEs?	95 (63.8)	54 (36.2)

Table 2 depicts the knowledge of surgeons regarding materiovigilance. About 67.8% of participants correctly identified India's Materiovigilance Programme (MvPI), and 75.2% were aware that all healthcare professionals are eligible to report device-related adverse events. However, fewer participants could correctly identify device categorization (49.7%) and events that need not be reported (46.3%), highlighting gaps in technical knowledge and the need for targeted training to strengthen effective implementation in surgical practice.

Table 3: Attitude of study participants towards materiovigilance (*n*=149).

Attitude Assessment Questions	Response	n (%)
1. Do you think materiovigilance is as important as pharmacovigilance for patient safety?	Strongly agree	95 (63.8)
	Agree	40 (26.8)
	Disagree	10 (6.7)
	Strongly disagree	4 (2.7)
2. Do you agree that surgical devices and instruments can cause adverse events during or after procedures?	Strongly agree	103 (69.1)
	Agree	35 (23.5)
	Disagree	8 (5.4)
	Strongly disagree	3 (2.0)
3. Do you agree that reporting surgical device–related adverse events can improve patient safety and surgical outcomes?	Strongly agree	100 (67.1)
	Agree	30 (20.1)
	Disagree	15 (10.1)
	Strongly disagree	4 (2.7)
4. Do you believe it is the responsibility of surgeons to report every device-related adverse event encountered in surgical practice?	YES	127 (85.2)
	NO	22 (14.8)
5. Should the reporting of surgical device–related adverse events be made mandatory in hospitals?	YES	120 (80.5)
	NO	29 (19.5)

Table 3 summarizes the attitudes of surgeons towards materiovigilance. Most participants recognized its importance, with 63.8% strongly agreeing that it is as significant as pharmacovigilance, and 69.1% acknowledging that surgical devices can cause adverse events. Furthermore, 85.2% felt reporting is a surgeon's responsibility, and 80.5% supported making reporting mandatory. Overall, the findings reflect a positive attitude among surgeons and their willingness to engage in reporting practices to enhance patient safety.

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Table 4: Response of participants regarding the practice of materiovigilance (*n*=149)

Practice-related questions	Response	n %
1. Have you ever encountered an adverse event related to a medical device in surgery?	YES	72 (48.3)
	NO	77 (51.7)
2. If yes, did you report the adverse event to the concerned authority or system?	YES	38 (25.50)
	NO	111 (74.49)
3. Have you ever been trained on how to report a medical device-induced adverse event?	YES	29 (19.5)
	NO	120 (80.5)

Table 4 highlights that 48.3% of surgeons had encountered a device-related adverse event, yet only 25.5% of those reported it to the appropriate authority. Additionally, 80.5% of participants had never received formal training on reporting device-related adverse events. These findings indicate considerable gaps in the practical application of materiovigilance, underscoring the need for structured training programs to improve reporting and enhance patient safety in surgical care.

Figure 1: Mean KAP Scores of Surgeons

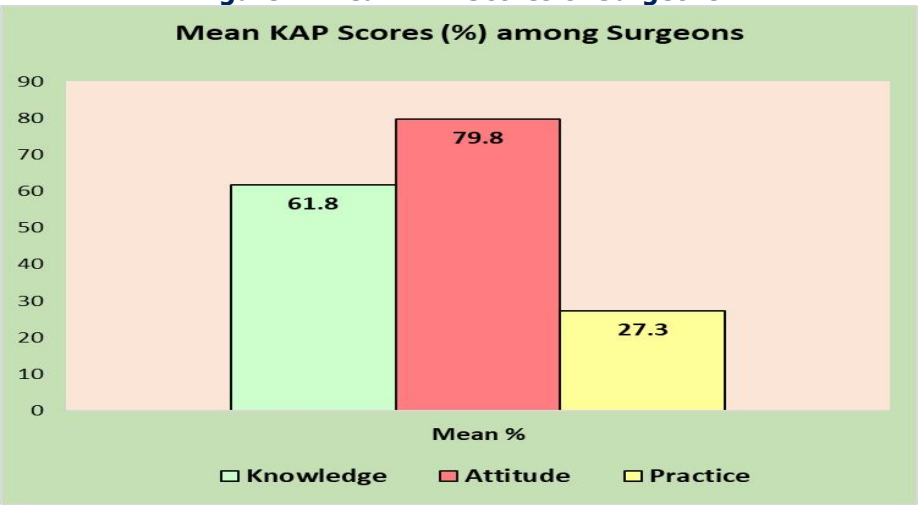

Figure 1: The overall mean scores of Knowledge, Attitude, and Practice among the 149 surgeons are presented in Figure 1. The mean Knowledge score was 61.8 ± 13.2%, indicating moderate awareness of materiovigilance. Attitude scores were higher, with a mean of 79.8 ± 11.1%, reflecting generally positive perceptions regarding the importance of materiovigilance in surgical practice. In contrast, Practice scores were low, with a mean of 27.3 ± 14.5%, highlighting a gap between knowledge, attitudes, and actual reporting behaviors. These findings suggest that while surgeons are aware of and value materiovigilance, implementation into routine practice remains limited.

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Figure 2: Knowledge, Attitude, and Practice: Reporters vs. Non-Reporters

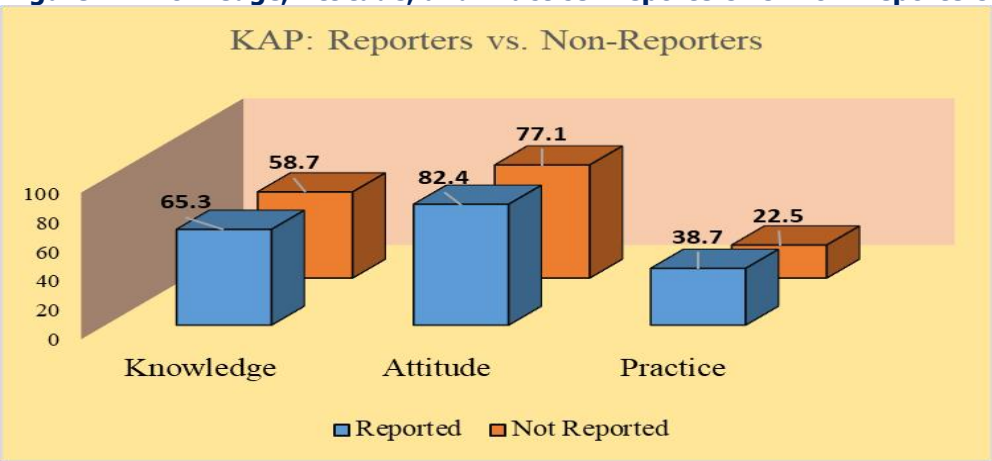

Table 5: Comparison of KAP Scores Between Reporting and Non-Reporting Surgeons

KAP Component	Reported Mean ± SD	Not Reported Mean ± SD	t-test p-value
Knowledge	65.3 ± 12.1	58.7 ± 13.8	0.018
Attitude	82.4 ± 10.5	77.1 ± 11.2	0.024
Practice	38.7 ± 15.6	22.5 ± 12.3	0.001

Fig. 2, Table 5 shows the results of Independent t-tests that were conducted to compare Knowledge, Attitude, and Practice (KAP) scores between surgeons who reported device-related adverse events (n = 38, 25.5%) and those who did not (n = 111, 74.5%). Reporters had higher mean Knowledge (65.3 ± 12.1% vs. 58.7 ± 13.8%, p = 0.018) and Attitude scores (82.4 ± 10.5% vs. 77.1 ± 11.2%, p = 0.024). Practice scores were low overall but higher in reporters (38.7 ± 15.6% vs. 22.5 ± 12.3%, p = 0.001). Since all *p*-values were below the conventional threshold of 0.05, these differences are statistically significant, suggesting that surgeons who engage in reporting not only have better knowledge and attitudes toward materiovigilance but also show greater, though still limited, practical application.

Discussion

The present study provides valuable insights into the knowledge, attitudes, and practices of surgeons towards materiovigilance. The demographic profile revealed a clear male preponderance (79.9%), which is consistent with previous studies [8], where 78.2% of participants were male. In contrast, studies conducted among mixed healthcare professionals demonstrated a more balanced distribution, with greater female representation [9]. Most participants belonged to the 41–50 years age group (36.24%), reflecting the mid-career stage when surgeons are actively engaged in high surgical loads and decision-making responsibilities, similar to previous findings [8]. With respect to specialties, General Surgery (35.7%) and Orthopedics (20.8%) dominated in the study, aligning with earlier reports [8, 9].

In terms of knowledge, the results of the survey highlight both strengths and gaps. Nearly 67.8% correctly identified the Materiovigilance Programme of India (MvPI), higher than the 31.4% and 40% awareness reported in previous studies [8, 10]. Similarly, 75.2% recognized that all healthcare professionals are eligible to report device-

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related adverse events, comparable to 70.5% in earlier research [8]. However, only 49.7% could correctly identify Category A devices, and 46.3% knew which events need not be reported, highlighting limited awareness of technical details. This is comparable to 44.9% in other studies [9]. Such gaps suggest that while overall awareness of materiovigilance is improving, surgeons require targeted training on the operational and regulatory aspects of the program to enhance effective implementation in surgical practice.

The attitudes of surgeons towards materiovigilance were overwhelmingly positive. In the study, 63.8% strongly agreed that materiovigilance is as important as pharmacovigilance, and 69.1% strongly agreed that surgical devices can cause adverse events. These findings are comparable to those reported in previous studies [9, 11], where 96.8% of healthcare professionals recognized the potential for device-related harm and 72.4% emphasized the importance of materiovigilance for patient safety. Furthermore, 85.2% of surgeons felt it was their responsibility to report device-related adverse events, closely matching earlier findings [8, 12]. Importantly, 80.5% of participants supported mandatory reporting, which is in line with previously reported rates [8, 13]. Collectively, these results highlight a strong readiness among surgeons to adopt materiovigilance, provided that systemic and educational barriers are effectively addressed.

Despite good knowledge and positive attitudes, actual practices were suboptimal. In the study, 48.3% of surgeons had encountered a device-related adverse event, but only 26.2% reported it. This is higher than the 9% reported in previous research but still below desired levels. Lack of formal training was a major factor, with 80.5% of participants never having received structured instruction. Similar trends have been observed in earlier studies [8, 9, 14, 15], where high awareness did not consistently translate into reporting practices. These findings highlight that despite awareness and positive attitudes, practical barriers continue to limit active reporting.

Generalizability.

The findings of this study primarily reflect the knowledge, attitudes, and practices of surgeons working in urban healthcare settings in Navi Mumbai. They are most applicable to similar tertiary care hospitals in India. Inclusion of surgeons from multiple specialties and age groups enhances the representativeness within this context. However, caution is needed when extrapolating these results to rural hospitals, other regions, or healthcare professionals outside surgical practice, as variations in training, reporting culture, and access to materiovigilance programs may influence KAP outcomes.

Conclusions.

Overall, our findings underscore a paradox frequently noted in pharmacovigilance research as well: good knowledge and positive attitudes do not necessarily translate into effective practice. While surgeons in the study demonstrated better awareness of MvPI compared to earlier reports, actual reporting remained low, reflecting persistent gaps. Interventions such as structured workshops, integration of materiovigilance training into surgical curricula, and simplified reporting mechanisms could help bridge this gap. Studies have shown that educational interventions significantly improve knowledge and reporting rates of adverse events, and similar approaches could be effectively applied to materiovigilance.

Limitations.

This study was conducted only among surgeons in Navi Mumbai, limiting generalizability to other regions or rural healthcare settings. The cross-sectional design captures knowledge, attitudes, and practices at a single point in time, and some surgical specialties were underrepresented, which may affect applicability to those groups.

Recommendations.

Regular training on materiovigilance, user-friendly reporting platforms, and integration into surgical practice and curricula are recommended. Hospitals should implement or reinforce policies to make reporting device-related adverse events a standard practice, and periodic audits can help improve compliance and enhance patient safety.

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Conflict of Interest

The authors declare no conflict of interest.

Availability of Data

The datasets generated and analyzed during the study are available from the corresponding author upon reasonable request.

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Dr. Veena Rane: Clinical Researcher, contributing to data presentation and validation of study findings.

Yuvraj Sawant, III-year MBBS student, D Y Patil Medical College, Navi Mumbai, involved in research and pharmacoeconomic studies.

Dr.Nidhi Hrishikesh Vadhavekar, Intern, D Y Patil Medical College, Navi Mumbai, is involved in research, pharmacovigilance, and pharmacoeconomic studies.

Author's Contribution

Dr. Pradnya Deolekar: Conceptualization, study design, supervision, and manuscript drafting.

Dr. Kavitha V. Dongerkery: Questionnaire preparation, data analysis, interpretation, and manuscript review.

Dr. Sandesh Deolekar: Clinical input and critical revision of the manuscript.

Dr. Movva Navya, Atharv Dahibhate, Prateek D. T., Akash Sinha, Yuvraj Sawant, Nidhi Hrishikesh Vadhavekar: Data collection, literature review, and assistance in manuscript preparation.

Veena Rane: Drafting tables, Data presentation.

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