ORIGINAL RESEARCH

A Questionnaire Study on The Knowledge, Attitude, and the Practice of Materiovigilance Among the Healthcare Professionals in A Teaching Hospital in Maharashtra

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ABSTRACT
Background: Materiovigilance is a critical aspect of patient safety, focusing on the detection, assessment, and prevention of adverse events associated with medical devices. Despite its significance, there is limited research on the knowledge, attitude, and practices (KAP) of healthcare professionals regarding Materiovigilance in Indian settings. This study aims to assess the KAP among healthcare professionals in a teaching hospital in Maharashtra. **Methods:** A cross-sectional, questionnaire-based study was conducted among 200 healthcare professionals, including doctors and nurses, at a teaching hospital in Maharashtra. The questionnaire assessed demographic details, knowledge, attitudes, and practices related to Materiovigilance. Data were analyzed using descriptive and inferential statistics, with Chi-square tests employed to evaluate the significance of associations between responses. **Results:** The study revealed that 63% of participants correctly identified the ongoing program in India for monitoring adverse events due to medical devices, while 83% correctly identified the regulatory body responsible for adverse event monitoring. However, only 52% were aware of the national center for adverse drug reaction monitoring. Attitudinal responses showed strong agreement on the importance of Materiovigilance, with 96% acknowledging that medical devices could cause adverse events. Despite this, practical engagement was limited, with only 26% reporting adverse events and 22% having attended workshops or CMEs on device safety. Statistical analyses demonstrated significant associations ($p < 0.05$) between knowledge, attitudes, and certain practices. **Conclusion:** The study highlights significant gaps between theoretical knowledge and practical application of Materiovigilance among healthcare professionals. While attitudes towards Materiovigilance are positive, there is a need for targeted training programs and institutional support to enhance reporting practices and overall engagement with Materiovigilance protocols. Strengthening Materiovigilance systems can contribute to improved patient safety and medical device efficacy.
Keywords: Materiovigilance, healthcare professionals, adverse event reporting.

INTRODUCTION

Materiovigilance, an essential component of patient safety and healthcare quality, refers to the systematic monitoring and evaluation of the safety and performance of medical devices. This aspect of healthcare is crucial in preventing adverse incidents and ensuring the efficacy of medical interventions. In teaching hospitals, where the nexus of healthcare delivery meets medical education, understanding the knowledge, attitudes, and practices (KAP) of healthcare professionals regarding Materiovigilance is fundamental.

Despite the significance of Materiovigilance, its implementation and the level of awareness among

healthcare providers often vary, influenced by the regulatory landscape, institutional policies, and the training of the healthcare workforce. The overarching aim of this study was to examine the knowledge, attitudes, and practices concerning Materiovigilance among healthcare professionals at a teaching hospital in Maharashtra. This research sought to provide empirical data that could be instrumental in shaping educational programs, institutional policies, and perhaps even influencing national healthcare regulations concerning the use of medical devices.

The introduction of medical devices into clinical practice has profoundly impacted patient care, offering new and innovative methods to diagnose, treat, and manage diseases. However, the integration of these technologies also presents potential risks and adverse outcomes, underscoring the need for robust Materiovigilance systems. Research indicates varying levels of Materiovigilance activities across different regions and healthcare systems, with some settings showing well-established practices and others in the nascent stages of implementation.[1,2]

In India, the concept of Materiovigilance has been evolving, with several initiatives aimed at enhancing the safety profiles of medical devices. The Indian Pharmacopeia Commission, under the aegis of the Ministry of Health and Family Welfare, has spearheaded efforts to develop a structured Materiovigilance program akin to pharmacovigilance.[3] This study is aligned with these broader national efforts, aiming to gauge the current landscape of Materiovigilance practices within a teaching hospital setting.

A literature review revealed that healthcare professionals' adherence to Materiovigilance protocols is often hindered by a lack of awareness and training regarding medical device-related complications and the reporting mechanisms [4, 5]. Moreover, cultural factors within healthcare institutions can either enable or inhibit proactive Materiovigilance practices. It is therefore crucial to investigate these elements comprehensively.[6,7]

Aims

To study the knowledge, attitude, and the practice of Materiovigilance among the healthcare professionals in a teaching hospital in Maharashtra.

Objectives

1. To evaluate the knowledge, attitude, and practices (KAP) of the healthcare professionals about Materiovigilance in Tetiary care teaching Hospital.
2. To evaluate the knowledge of healthcare professionals regarding Materiovigilance within a tertiary care teaching hospital in Maharashtra.
3. To assess the attitudes and practices related to Materiovigilance among these professionals, focusing on adherence to and awareness of ADR reporting.

MATERIAL AND METHODOLOGY

Source of Data

The primary data for this study was collected through a structured questionnaire designed to evaluate the knowledge, attitudes, and practices regarding Materiovigilance among healthcare professionals, including doctors and nurses, at a teaching hospital.

Study Design

This was a prospective, cross-sectional questionnaire-based study. The study design facilitated the assessment of current practices within a definitive time frame, allowing for a clear snapshot of ongoing Materiovigilance activities.

Study Location

The study was conducted at S.R.T.R. Government Medical College and Hospital, Ambajogai, Dist. Beed, Maharashtra, which provided a diverse sample of healthcare professionals working in a teaching hospital environment.

Study Duration

The data collection phase of the study spanned from October 2023 to December 2023.

Sample Size

The sample size was predetermined to be 200 healthcare professionals to ensure statistical relevance and the ability to generalize findings to similar settings.

Inclusion Criteria

Participants included were doctors and nurses who:

- Were currently employed at the hospital during the study period.
- Provided written informed consent to participate in the study.

Exclusion Criteria

Healthcare professionals were excluded if they:

- Did not wish to participate in the study.

Procedure and Methodology

Participants were approached by the research team and briefed about the purpose of the study. Upon agreeing to participate and providing consent, they were asked to complete the questionnaire, which included demographic questions and sections aimed at assessing their knowledge, attitudes, and practices related to Materiovigilance. The questionnaire comprised 15 questions divided into three sections, each containing five questions relevant to the respective KAP domains.

Sample Processing

Responses were anonymized and coded before analysis to maintain confidentiality and facilitate data processing.

Statistical Methods

Data were analyzed using descriptive and inferential statistics. Frequency distributions were used to describe categorical variables, while means and standard deviations were employed for continuous variables. Chi-square tests and t-tests were used to explore relationships between demographic factors and KAP scores.

Data Collection

Data collection included demographic information such as gender and age, along with professional categorization (doctor or nurse), which provided insights into the distribution and variability of KAP among different groups within the healthcare setting.

OBSERVATION AND RESULTS

Table 1: Demographic Details of the Healthcare Professionals

Category	Number (n)	Percentage (%)
Gender - Male	94	47%
Gender - Female	106	53%
Age 25-30	60	35%
Age 30-40	58	29%
Age 40-50	54	27%
Age 50-60	32	16%
Professional - Doctors	96	48%
Professional - Nurses	104	52%

Table 1: Demographic Details of the Healthcare Professionals reveals the distribution of gender, age, and professional status among the healthcare professionals surveyed. There were slightly more females (53%) than males (47%). Age distribution shows a majority in the 25-40 age group, making up over half of the participants, with younger (12%) and older professionals (16%) less represented. The professional breakdown was nearly even with 48% doctors and 52% nurses.

Table 2: Knowledge Related Questions and Responses

Knowledge Related Questions	Correct Response (n)	Incorrect Response (n)	p-value	Significance
What is the ongoing program in India for monitoring adverse events due to medical devices?	126	74	0.00024	Significant
What is the basis of classifying medical devices into different categories (A, B, C, D) in India?	134	66	0.000002	Significant
In India which Regulatory body is responsible for monitoring of ADR's due to medical devices	166	34	< 0.000001	Significant
The National centre for adverse drug reaction due to medical devices monitoring is located in	104	96	0.5716	Not significant
A serious adverse event due to medical device in India should be reported to the regulatory body within	86	114	0.0477	Significant

Table 2: Knowledge Related Questions and Responses assesses the knowledge level of healthcare professionals regarding Materiovigilance. It shows significant knowledge gaps with most questions showing a significant majority able to answer correctly. Specifically, substantial knowledge was evident on the regulatory body responsible for monitoring ADRs due to medical devices and the basis of classifying medical devices, with p-values indicating strong statistical significance. However, knowledge about the location of the national centre for adverse drug reaction monitoring did not show a significant difference between correct and incorrect answers, suggesting a potential area for improvement in awareness.

Table 3: Attitude-related Questions and Responses

Attitude-related questions	Correct Response (n)	Incorrect Response (n)	p-value	Significance
Do you think medical devices can cause adverse events in the patient?	192	8	< 0.000001	Significant
Do you think Materiovigilance should be taught in detail to healthcare professionals	168	32	< 0.000001	Significant
What is your opinion about establishing ADR monitoring centre for medical devices in every hospital	144	56	< 0.000001	Significant
Have you anytime read any article on prevention of adverse drug reactions due to medical devices	128	72	0.000075	Significant

Do you know regarding the existence of MvPI	112	88	0.0897	Not significant
Do you think reporting of adverse event due to medical device will enhance patient safety?	178	22	< 0.000001	Significant

Table 3: Attitude-related Questions and Responses explores attitudes towards Materiovigilance. The overwhelming majority believe that medical devices can cause adverse events and that Materiovigilance should be detailed in their training. A significant number also support the establishment of ADR monitoring centers in hospitals and feel that reporting adverse events enhances patient safety. However, less consensus was seen on the awareness of the Materiovigilance program in India (MvPI), where the difference between correct and incorrect responses was not statistically significant.

Table 4: Practice-related Questions and Responses

Practice-related questions	Yes (n)	No (n)	p-value	Significance
Have you ever encountered any adverse events due to medical device during your practice	56	144	< 0.000001	Significant
Have you ever seen the ADR reporting form of Materiovigilance	82	118	0.0109	Significant
Have you ever reported the ADR due to medical devices	52	148	< 0.000001	Significant
Do you monitor the patients for any adverse outcome of implanted device beyond the recovery period?	68	132	0.000006	Significant
Have you ever attended any workshop or CME focused on safety of medical device	44	156	< 0.000001	Significant

Table 4: Practice-related Questions and Responses delves into the practical experiences and actions of healthcare professionals concerning Materiovigilance. It reveals that while a majority have not personally encountered adverse events, nor reported any such events, there is a significant awareness and acknowledgment of the importance of monitoring and reporting, as evidenced by statistically significant p-values. However, fewer professionals have attended workshops or CMEs focused on medical device safety, suggesting an area where professional development might be enhanced.

DISCUSSION

Table 1: Demographic Details of the Healthcare Professionals: This table illustrates a balanced gender distribution among healthcare professionals, with a slight female majority. The age distribution highlights a concentration of professionals in the mid-career stages (25-40 years), which is typical in healthcare settings where experience plays a crucial role in patient care and decision-making. The professional distribution is evenly split between doctors and nurses, which reflects the collaborative nature of healthcare teams. This demographic makeup is consistent with global healthcare workforce trends where the representation of women and the division between nursing and medical staff are key factors in healthcare delivery Tantia R *et al.*(2023)[8]& Srinivas M *et al.*(2023)[9].

Table 2: Knowledge Related Questions and Responses: The responses to knowledge-related questions reveal significant awareness about the regulatory frameworks and classification of medical devices in India, similar to findings from other studies emphasizing the importance of regulatory knowledge in clinical practice Modi K *et al.*(2023)[10]. However, the knowledge about the location of the national monitoring center and the protocol for reporting severe adverse events was less robust, suggesting potential areas for improvement. This aligns with studies suggesting that while healthcare professionals may be aware of overarching regulatory standards, specific procedural knowledge may lag Rehman S *et al.*(2023)[11]& Shenoy AK *et al.*(2023)[12]

Table 3: Attitude-related Questions and Responses: The strong consensus on the potential risks associated with medical devices and the importance of Materiovigilance education highlights a positive attitude towards patient safety and professional development. The high level of agreement on the need for ADR monitoring centers in hospitals reflects a proactive approach to patient safety, mirroring sentiments found in broader healthcare studies that advocate for more robust safety monitoring systems Meher BR *et al.*(2023)[13] &Attri LK *et al.*(2023)[14]. The variability in awareness of the Materiovigilance program in India (MvPI) suggests that while the concept is gaining traction, more targeted educational efforts are needed, as also noted in other regional studies Gayathri V *et al.*(2022)[15]

Table 4: Practice-related Questions and Responses: The responses indicate that actual encounter rates with adverse events and participation in formal training or workshops are low, pointing to a discrepancy between awareness and real-world experiences. This gap underscores findings from similar research, which indicates that while healthcare professionals often recognize the theoretical importance of safety practices, actual engagement may be limited by

various barriers including lack of time, resources, or institutional support Shaik R *et al.*(2021)[16]& Kalaiselvan V *et al.*(2023)[17]

CONCLUSION

This study highlights the knowledge, attitudes, and practices (KAP) regarding Materiovigilance among healthcare professionals in a teaching hospital in Maharashtra. While the findings reveal commendable awareness of the overarching principles and significance of Materiovigilance, specific procedural knowledge, particularly related to adverse device reaction (ADR) reporting protocols and the Materiovigilance Program of India (MvPI), remains limited.

The positive attitudes towards the role of Materiovigilance in enhancing patient safety and the need for establishing ADR monitoring systems in hospitals reflect a proactive mindset among the participants. However, the disparity between theoretical knowledge and practical application is evident, as few healthcare professionals have encountered adverse events or actively participated in reporting mechanisms and related training programs.

These findings emphasize the need for targeted interventions, including workshops, continuous medical education (CME), and institutional support, to bridge the gap between awareness and practice. Strengthening Materiovigilance training programs and integrating them into routine professional development could significantly enhance patient safety outcomes and the effective use of medical devices.

In conclusion, while the foundation for Materiovigilance awareness is robust, fostering a culture of active engagement and institutional support is essential to fully integrate these practices into everyday healthcare delivery.

LIMITATIONS OF STUDY

1. **Single-Center Study:** This study was conducted in a single teaching hospital in Maharashtra, which may limit the generalizability of the findings to other healthcare institutions or regions with different demographic and professional profiles.
2. **Self-Reported Data:** The study relied on self-reported responses to a questionnaire, which may be subject to social desirability bias, where participants might provide responses they perceive as favorable rather than reflecting their true knowledge, attitudes, or practices.
3. **Cross-Sectional Design:** As the study used a cross-sectional design, it captures data at a single point in time. It does not account for changes in knowledge, attitudes, or practices over time or the impact of interventions such as training sessions.
4. **Limited Scope of Questions:** While the questionnaire covered essential aspects of Materiovigilance, it may not have comprehensively addressed all potential dimensions of knowledge, attitudes, and practices related to medical device safety.
5. **Potential Non-Response Bias:** Healthcare professionals who did not participate in the study may have different levels of knowledge, attitudes, or practices compared to those who participated, potentially introducing non-response bias.
6. **Exclusion of Other Healthcare Roles:** The study focused primarily on doctors and nurses, excluding other healthcare professionals (e.g., pharmacists, technicians) who may also play crucial roles in Materiovigilance.
7. **Limited Exploration of Barriers:** The study did not delve deeply into the systemic or institutional barriers that might hinder healthcare professionals' engagement with Materiovigilance, such as workload, lack of reporting infrastructure, or insufficient training.
8. **Quantitative Nature of the Study:** The use of a structured questionnaire limited the exploration of qualitative insights, such as personal experiences and nuanced perspectives regarding Materiovigilance practices.

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