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KNOWLEDGE, ATTITUDE, AND PRACTICE OF MATERIOVIGILANCE AMONG THE HEALTHCARE PROFESSIONALS IN A TERTIARY CARE HOSPITAL – A QUESTIONNAIRE-BASED STUDY

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ABSTRACT

Background: Materiovigilance is a methodical surveillance of medical devices associated with adverse events, and it is important to ensure the safety of the patients. Regardless of these attempts, there are major difficulties regarding the awareness and integration of materiovigilance among the doctors. The objectives of the study is to assess the knowledge and attitude and practices among the healthcare professionals regarding materiovigilance, and to identify the barriers and suggestions for improving adverse event reporting are the objectives of the study. **Materials and Methods:** This cross-sectional study was conducted among 102 doctors from various specialities using a structured questionnaire via Google Forms. The survey assessed participants' knowledge, attitude, and practice toward materiovigilance, along with indications for enhancing the reporting. Data was presented as mean and standard deviation, and median with interquartile range for continuous variables and as percentages for categorical variables. **Result:** Among 102 participants, 54 (52.9%) residents and 48 (47.1%) faculty, the mean knowledge, attitude, and practice scores were 4.4 ± 1.5, 5.2 ± 0.8, and 1.1 ± 1.2, respectively. Faculty had significantly higher knowledge than residents ($p = 0.002$), with no difference in attitude ($p = 0.911$) or practice ($p = 0.460$). Knowledge varied across specialities ($p = 0.027$). Faculty showed better understanding of materiovigilance concepts and higher reporting activity. Key suggested improvements for reporting were training 50 (49.02%), mandatory reporting 20(19.60%), and continuing medical education programs 16 (15.69%). **Conclusion:** Healthcare professionals show good awareness and attitude toward materiovigilance, but reporting remains low. Enhancing training, curriculum integration, and supportive reporting systems is essential to improve practice and ensure patient safety.

INTRODUCTION

The organised surveillance of adverse events pertaining to medical devices and their evaluation is a crucial part of medical treatment, focusing on securing the well-being of the patients and enhancing the performance of the devices.[1] Materiovigilance is a comprehensive system for monitoring, identifying, collecting, reporting, and evaluating undesirable events related to the performance of medical equipment.[2] The motive of materiovigilance is to recognise and prevent any likely danger related to medical equipment.[3] In recent years, there has been a rapid increase in the utilisation of medical devices for the diagnosis, treatment and prevention of many diseases; hence, systematically monitoring the undesirable events related to medical equipment is an important priority in India.[3,4] To supervise the secure usage of medical instruments, the Ministry of Health and Family Welfare authenticated the Materiovigilance Programme of India.[5] Regardless of these attempts, there are major difficulties regarding the awareness and integration of materiovigilance among the doctors.[6]

In order to accomplish the goals of the materiovigilance programme, medical professionals play an important part, and their awareness regarding the reporting of undesired events is crucial towards prompt recognition and alleviation of

hazards related to medical equipment. Studies have revealed that a considerable percentage of undesired events are not reported, which may hamper the effective performance of the programme regarding materiovigilance.[7] The idea of materiovigilance includes many extensive activities targeted at security and efficiency of medical devices, which are ongoing monitoring of the reliability and equipment functionality after release into the market, reporting of adverse events and the uninterrupted evaluation of positive therapeutic outcomes of a medical device in comparison with its potential risks.[6] In spite of the implementation of materiovigilance systems, underreporting of medical device-related adverse events remains a significant challenge. This persistent issue is primarily attributed to inadequate perception among healthcare professionals, insufficient training on reporting protocols and insufficient support and encouragement from the institution for active surveillance practices.[8] Underreporting or non-reporting of medical device related adverse event is rather common. The Food and Drug Administration has shared information indicating that only 0.5 percent of adverse events associated with the medical device are reported.[9] The understanding of the awareness and practice of doctors towards materiovigilance is essential to identify gaps and develop targeted strategies for improvement. The present study was aimed at assessing knowledge regarding materiovigilance, attitude and practices related to materiovigilance among medical professionals in a tertiary care hospital and to identify key barriers for the effective reporting of undesired events associated with medical devices.

MATERIALS AND METHODS

The present questionnaire-based study was done in a South Indian tertiary care hospital for six months from June 2023 to November 2023. This study was commenced after acceptance from the Institutional Human Ethics Committee (1968/PHARM/ TVMC). Written informed consent was secured from all the doctors before including them in the study.

Medical professionals working in a study centre involved in direct patient care and the use or monitoring of medical devices were included in the study. Medical professionals unwilling to participate or with incomplete responses were excluded from the study. A total of 125 doctors were enrolled using a convenience sampling technique. Sample size calculation was based on previous similar studies and the estimated prevalence of adequate knowledge about materiovigilance.

Sample size estimation: Based on the percentage of awareness of materiovigilance among the health care professionals in a previous study, and with a 95% confidence interval and precision of 10% the minimum sample size is estimated to be 100.

Data Collection Tool: A structured, pre-validated questionnaire was used for data collection. The questionnaire had four sections, and they are knowledge regarding materiovigilance, attitude towards the documenting of undesired events associated with medical devices, current reporting practices and possible ways to improve the documenting of medical device-related undesired events. Multiple-choice questions for the knowledge section, attitude and practice sections had direct yes or no questions.

Study procedure: The participants were approached in their respective departments and provided with the questionnaire after informed consent. They were given adequate time to respond, and confidentiality was maintained throughout the process.

Statistical analysis: Data collected was entered into MS Excel, and analysis was done using SPSS 21.0 version. Data were presented as mean and standard deviation, and median with interquartile range for continuous variables and as percentages for categorical variables. The Mann-Whitney U test was used to compare two group medians, and the Kruskal-Wallis test was used for more than two group medians. A chi-square test was done to find out the association between categorical variables. A P value of less than 0.05 was considered significant.

RESULTS

A total of 102 participants were included in the study, comprising 54 (52.9%) residents and 48 (47.1%) faculty members. Participants represented various medical specialties, with the highest representation from Medicine 17 (16.7%), followed by Surgery 15 (14.7%), and Pediatrics 11 (10.8%) [Table 1]. The mean and median scores for knowledge, attitude, and practice towards materiovigilance are shown in [Table 2]. The mean knowledge score was 4.4 ± 1.5, attitude score 5.2 ± 0.8, and practice score 1.1 ± 1.2. These results indicate that while the participants generally had a positive attitude, their knowledge and practice levels were relatively lower.

The comparison of knowledge, attitude, and practice between residents and faculty using the Mann-Whitney U test is presented in [Table 3]. A statistically significant difference in knowledge scores was observed between residents and faculty ($p = 0.002$). The effect size is 0.309, indicating a moderate difference, with faculty demonstrating higher knowledge scores than resident. There was no statistically significant difference in attitude scores between the two groups ($p = 0.911$). The effect size is 0.011, which is negligible, indicating similar attitudes among residents and faculty. No significant difference was found in the practice scores between residents and faculty ($p = 0.460$). The effect size of 0.073 is small and not meaningful, indicating that practice patterns are similar across

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groups. The Mann-Whitney U test revealed that faculty had significantly higher knowledge scores than residents, with a moderate effect size. No significant differences were found between the two groups in attitude or practice scores, and the effect sizes were negligible, suggesting similar distributions for these domains among residents and faculty

A Kruskal-Wallis test was conducted to compare knowledge, attitude, and practice scores among different medical specialties. The test revealed a statistically significant difference in knowledge scores between specialties with a degree of freedom of 17.16, P value of 0.027 and effective size of 0.11, indicating at least one specialty had a different distribution of knowledge scores compared with the others. However, for attitude, the test did not show a significant difference, the degree of freedom is 7.31, p value is 0.467 and effective size is -0.003 indicating that the median attitude scores were statistically similar across specialties and for practice, the results showed no significant difference with degree of freedom of 9.46, p value of 0.265 and effective size of 0.02 suggesting that only about 2.4% of the variance in practice rank scores could be attributed to specialty type [Table 4].

Table 1: Characteristics of study participants

Parameters	Number of Participants (n = 102)	Percentage (%)
Cadre		
— Resident	54	52.9%
— Faculty	48	47.1%
Speciality		
— Medicine	17	16.7%
— Surgery	15	14.7%
— Paediatrics	11	10.8%
— Ophthalmology	10	9.8%
— Biochemistry	10	9.8%
— Orthopaedics	9	8.8%
— Pharmacology	9	8.8%
— Pathology	8	7.8%
— Radiology	8	7.8%
— Microbiology	5	4.9%

Faculty demonstrated significantly higher knowledge on key aspects of materiovigilance, including the definition (p = 0.008), objectives of the program (p = 0.026), and identification of the national coordinating centre (p = 0.019). No significant differences were observed regarding medical device classification, moderate-risk device identification, or reporting methods. Both groups showed a highly positive attitude toward materiovigilance. However, the faculty exhibited a significantly stronger agreement that reporting adverse events is a professional duty (p = 0.031). Faculty were significantly more likely to have reported adverse events to a medical device monitoring centre (p = 0.049).

[Table 5] shows the methods to improve the reporting of adverse events; the majority of the study participants suggested that the measure was the training of healthcare professionals, which was cited by 50 (49.0%) respondents. This was followed by making reporting compulsory by 20 (19.6%) respondents and continuing medical education programs or workshops by 16 (15.7%) respondents. A smaller proportion of 13 (12.8%) respondents emphasised the availability of reporting forms in clinical areas as a practical facilitator.

Table 2: The mean and median scores for knowledge, attitude, and practice towards materiovigilance

Variable	Mean ± SD	Median (IQR)
Knowledge	4.4 ± 1.5	4.0 (3.0, 6.0)
Attitude	5.2 ± 0.8	5.0 (5.0, 6.0)
Practice	1.1 ± 1.2	1.0 (0.0, 2.0)

Table 3: Comparison between residents and faculty knowledge, attitude, and practice towards materiovigilance using the Mann–Whitney U test

Cader	Resident	Faculty	Mann Whitney U test P value	Effect size
Knowledge	4.0 (3.0, 5.0)	5.0 (4.0, 6.0)	0.002	0.309
Attitude	5.0 (5.0, 6.0)	5.0 (5.0, 6.0)	0.911	0.011
Practice	1.0 (0.0, 2.0)	1.0 (0.0, 2.0)	0.460	0.73

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Table 4: Comparison of knowledge, attitude and practices scores across specialties using Kruskal Wallis test

Speciality	Knowledge Median (IQR)	Attitude Median (IQR)	Practice Median (IQR)
Medicine	5.0 (4.0, 6.0)	5.0 (4.0, 6.0)	1.0 (1.0, 1.0)
Surgery	5.0 (3.0, 5.0)	5.0 (5.0, 6.0)	1.0 (0.0, 2.0)
Paediatrics	6.0 (5.0, 7.0)	6.0 (5.0, 6.0)	1.0 (1.0, 3.0)
Ophthalmology	4.5 (3.0, 6.0)	5.0 (5.0, 5.0)	0.0 (0.0, 2.0)
Orthopaedics	4.0 (4.0, 5.0)	5.0 (5.0, 5.0)	1.0 (0.0, 2.0)
Pathology	4.0 (3.0, 5.5)	5.0 (5.0, 5.5)	1.0 (1.0, 2.5)
Biochemistry	3.5 (3.0, 4.0)	5.0 (5.0, 6.0)	0.0 (0.0, 1.0)
Radiology	3.5 (2.5, 4.0)	5.0 (4.5, 6.0)	0.0 (0.0, 2.0)
Pharmacology	5.0 (4.0, 5.0)	5.0 (5.0, 6.0)	0.0 (0.0, 1.0)
Microbiology	4.0 (4.0, 4.0)	5.0 (5.0, 6.0)	1.0 (0.0, 1.0)
Kruskal Wallis test p value	0.027	0.467	0.265
Degree of freedom (df = 8)	17.16	7.31	9.46
Effect size η^2	0.11	-0.003	0.024

df is Degrees of freedom, p-value less than 0.05 is significant and η^2 is effect size IQR is Interquartile range.

Table 5: Parameters to improve the reporting of materiovigilance

Parameters	Response
Training of health care professionals	50 (49.02%)
Making reporting compulsory	20 (19.60%)
Continuing medical education or Workshop	16 (15.69%)
Availability of reporting forms in the ward	13 (12.75%)
Others	3 (2.94%)

DISCUSSION

This study assessed the knowledge, attitude, and practice regarding materiovigilance among residents and faculty members from various medical specialities in a tertiary care institution. The findings revealed that while the overall attitude towards materiovigilance was positive, the levels of knowledge and practice were relatively low among both groups. This highlights the existing gap between awareness and implementation of materiovigilance activities among healthcare professionals. The mean knowledge score of 4.4 ± 1.5 and the mean practice score of 1.1 ± 1.2 indicate inadequate familiarity with the concepts and reporting procedures related to materiovigilance. Shukla et al had reported similar findings in their study from India, which demonstrated limited knowledge and underreporting of medical device-associated adverse events among healthcare professionals. This may be attributed to inadequate training, lack of exposure to reporting systems, and limited emphasis on materiovigilance in medical education.[4]

The comparative analysis revealed a meaningful variation in the knowledge levels between residents and faculty members, faculty attaining higher median scores ($p = 0.002$). This may be explained by their extensive clinical experience, exposure to structured training programs, and active participation in safety committees. However, no notable variation emerged between the groups, suggesting that both residents and faculty share similar perceptions about the importance of reporting medical device-related adverse events, but these positive attitudes are not sufficiently translated into practice. A similar study had shown that there is a gap between attitude and practice on pharmacovigilance and materiovigilance, emphasising the need for effective implementation strategies.[10] Numerous associates are not aware of the significance of adverse event reporting, which has led to non-reporting and thereby incomplete data. Additionally, restricted foundation, like a lack of a nationwide electronic monitoring and reporting system, creates a considerable hurdle.[11] When analysed across specialities, participants from paediatrics demonstrated the highest knowledge scores, while those from biochemistry and radiology recorded the lowest. This difference may be explained by the frequent use of medical devices in paediatric care settings, increasing awareness of device safety issues. On the other hand, limited clinical exposure in laboratory-based or diagnostic specialities may account for their relatively lower knowledge levels. Medical professionals in Odisha demonstrated limited knowledge and extremely poor materiovigilance practices, despite a generally positive attitude.[12] Medical doctors in Gujarat had adequate awareness and an optimistic attitude, yet poor reporting practices persisted.[13] A comparative appraisal among pharmacists and other healthcare professionals in Kerala revealed that the majority of the participants had a positive attitude toward materiovigilance, and only a few participants demonstrated satisfactory practices.[14] The majority of the study participants conveyed their acceptance to report in the future, indicating a significant gap between positive attitudes and actual reporting behaviour.[15]

The item-wise analysis further revealed that faculty members had a significantly better understanding of the definition, objectives, and the national coordinating centre for materiovigilance. Nevertheless, both groups displayed gaps in recognising device classifications and moderate-risk

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devices, suggesting the need for structured teaching and hands-on sessions focusing on these aspects. Encouragingly, both residents and faculty strongly agreed that reporting adverse events is a professional responsibility, which indicates a readiness to participate in materiovigilance activities if adequate systems and support are in place. Regarding strategies to improve reporting, nearly half of the participants suggested regular training programs for healthcare professionals. Making reporting mandatory and organising continuing medical education sessions or workshops were also identified as key enablers. Furthermore, integrating the reporting of undesired events associated with medical equipment into the functions of existing adverse drug reaction monitoring centres can significantly strengthen the infrastructure and outreach of the materiovigilance program. Another study emphasised the importance of incorporating education on medical device safety and structured reporting guidelines into the undergraduate and postgraduate curriculum of healthcare disciplines to build a culture of safety and accountability from the ground up.[4] The constraint of this research lies in its single-centre design conducted in a meagre number of health care professionals, which may restrict broader applicability. The use of self-reported questionnaires may also introduce response bias, as participants might overestimate their attitudes or practices. Future multicentric studies involving larger and more diverse samples are recommended to assess the determinants of materiovigilance reporting.

CONCLUSION

Healthcare professionals in this study demonstrated good awareness and a positive attitude toward materiovigilance. However, actual reporting of medical device-related adverse events remains low. The gap between knowledge and practice is primarily due to inadequate training, limited awareness of reporting mechanisms, and insufficient institutional support. Strengthening educational programs, integrating materiovigilance into medical curriculum, and establishing user-friendly reporting systems with clear guidelines can enhance participation, improve medical device safety, and ultimately foster better patient care and clinical safety standards.

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