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Original Article

Materiovigilance: An Emerging Area for Exploration in Pharmaceutical Education-A Comparative Appraisal of Knowledge, Attitudes and Practices among Pharmacists and Healthcare Professionals

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ABSTRACT

Background: Materiovigilance is essential for monitoring the safety and performance of medical devices. This study aimed to assess the Knowledge, Attitudes and self-reported Practices (KAP) of healthcare professionals regarding the use and monitoring of implantable and other medical devices in and around Perinthalmanna, Kerala, India. **Materials and Methods:** This prospective observational study was conducted over a three-month period at KIMS Al-Shifa Super Specialty Hospital, Perinthalmanna. Healthcare professionals, including physicians, pharmacists, academicians, biomedical engineers, dentists, nurses, optometrists and students, were randomly selected to participate. Data were collected using a structured questionnaire that was validated through expert consultations and a pilot study. Quantitative data were analysed using descriptive statistics, Pearson correlation and the Likelihood ratio test, with qualitative responses undergoing thematic analysis. **Results:** Out of 700 distributed questionnaires, 600 complete responses were obtained (86% response rate). Nurses and students comprised the majority of respondents. Knowledge of materiovigilance was moderate, with 48% demonstrating satisfactory knowledge, 45.7% unsatisfactory and 6.3% poor knowledge. While attitudes were overwhelmingly positive (92.3% satisfactory), practices were less so, with only 26.8% satisfactory and 58.8% unsatisfactory. Knowledge was significantly associated with profession and years of experience ($p<0.05$). Practices were also associated with these factors, but attitudes were not. **Conclusion:** The study reveals that while healthcare professionals generally have a positive attitude towards materiovigilance, there is a significant gap in knowledge and practices. This indicates a need for enhanced training and educational programs to improve the effectiveness of materiovigilance in healthcare settings. Expanding awareness and incorporating materiovigilance into professional curricula could foster better reporting practices and enhance patient safety.

Keywords: Materiovigilance, Healthcare Professionals, Knowledge, Attitude, Practices, Medical Device Adverse Event.

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INTRODUCTION

Recognizing the ever-growing importance of medical devices in diagnosing, monitoring and managing various diseases, the World Health Organization (WHO) has called for the establishment of an essential diagnostics list, mirroring the existing list of essential medicines. This initiative highlights the crucial role these technologies play within contemporary healthcare delivery.[1] A medical device encompasses any instrument, apparatus, material, or software intended for a medical purpose, including diagnosis, prevention, treatment, or alleviation of disease.[2]

Despite their undeniable benefits, medical devices are not without inherent risks. Documented cases of device recall due to malfunctions or associated morbidity and mortality underscore the need for robust risk-benefit assessments. Ideally, a comprehensive monitoring mechanism should be implemented to evaluate these factors. Materiovigilance serves as such a system, focusing on the meticulous post-marketing surveillance of medical devices. This program facilitates the identification,

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collection and analysis of adverse events, enabling informed responses and the implementation of necessary safety corrective actions.[3]

Regulatory bodies categorize medical devices based on their potential risks. The US Food and Drug Administration (USFDA) employ a three-tier system: Class I for lowest risk, Class II for moderate risk and Class III for highest risk. Similarly, India's Central Drugs Standard Control Organisation (CDSCO) adopted a four-class system in 2017, with Class A denoting low risk and Class D signifying high risk. While advancements in medical technology offer undeniable benefits, concerns regarding device safety persist. High-risk devices like breast implants, pacemakers and artificial hips have been linked to adverse events, with a significant rise in reported cases documented in the 21st century. Furthermore, international investigations have uncovered the continued presence of hazardous medical devices in the global market, despite known risks. The magnitude of the problem is underscored by statistics revealing over 1.7 million injuries and 83,000 deaths globally attributed to faulty equipment in the past twelve years. India itself has reported over 1900 adverse events between 2015 and 2019, including fatalities and equipment malfunctions. These statistics highlight the critical need for robust risk management strategies, heightened vigilance and stricter regulations to ensure patient safety in the era of advanced medical technology.[4]

In response to the growing utilization of medical devices, the Materiovigilance Programme of India (MvPI) was established in 2015. This initiative aims to cultivate awareness among healthcare professionals regarding the significance of reporting Medical Device-Associated Adverse Events (MDAEs). Through this program, India strives to accumulate a robust and independent evidence-based safety database for medical devices. This data will serve as a cornerstone for recognizing trends in adverse events, informing regulatory decisions to ensure device safety and guiding best practices within the healthcare industry.[1]

Given the paramount importance of medical device safety for patient well-being, a comprehensive understanding of healthcare professionals' knowledge, attitudes and practices surrounding Materiovigilance is crucial. These healthcare professionals serve as the foundation of the Materiovigilance program by reporting adverse events associated with medical devices. However, existing literature suggests a concerning knowledge gap regarding Materiovigilance among this group. Therefore, to ensure the successful implementation of the Materiovigilance Programme of India (MvPI), this study aims to assess healthcare professionals' understanding of the program. By raising awareness on the significance of Materiovigilance within the healthcare community, the study strives to facilitate the program's successful execution.[5]

In spite of ongoing efforts by the Materiovigilance Programme of India to enhance the monitoring of medical device adverse events, underreporting remains a significant challenge. The primary cause of underreporting is the insufficient adherence to Adverse Event (AE) reporting practices among healthcare professionals.[6] Generally, HCPs are aware of the importance of reporting adverse events related to medical devices; however, there are gaps in their knowledge and understanding of the specific procedures and guidelines for reporting. Attitudes toward materiovigilance can vary, with some professionals recognizing its significance in improving patient safety, while others may view it as an additional administrative burden. In practice, the adherence to materiovigilance protocols is often inconsistent, influenced by factors such as workload, awareness of reporting systems and institutional support. To improve the effectiveness of materiovigilance, it is essential to provide ongoing education and training for HCPs, streamline reporting processes and foster a culture that prioritizes patient safety and encourages active participation in adverse event reporting.

With this background, the study was initiated to evaluate the Knowledge, Attitude and Practice (KAP) of Materiovigilance among different healthcare professionals. This KAP assessment aims to elucidate the current understanding and behaviors surrounding medical device safety reporting within various healthcare setting.[3] The objective of this study was to assess the KAP of materiovigilance among healthcare professionals of various settings.

MATERIALS AND METHODS

This was a prospective observational, questionnaire-based study at KIMS Al-Shifa super specialty hospital, Perinthalmanna, Kerala, India. Regional training center, Materiovigilance Programme to assess the knowledge, attitudes and self-reported practices of healthcare professionals regarding the use and monitoring of implantable and other medical devices from various institutes in and around Perinthalmanna. Study was conducted over a period of 3 month, from 10th April 2024 to 10th July 2024.

Participants were selected using a random sampling method to ensure representativeness and data were collected through online surveys or face-to-face interviews, depending on the accessibility and convenience of the target population. The study was included all healthcare professionals including physician, pharmacist, academician, biomedical engineer, dentist, nurse, optometrist and students present at the health facility during the study period were eligible to participate. Random sampling was employed by selecting participants from a pre-compiled list that included doctors, pharmacists and engineers from various healthcare and industry institutions. The sample was stratified to ensure proportional representation from each professional group based on their availability and participation rates. This approach aimed to maintain balanced inclusion across the professions

to accurately reflect their perspectives in the KAP study. This encompassed all individuals involved, whether directly or indirectly, in medical device adverse event reporting. Participants who were unwilling to participate in the study, as well as those who returned the questionnaire without providing any responses, were excluded from the study.

Ethical considerations were prioritized, with informed consent obtained from all participants and confidentiality assured. Quantitative data were analyzed using descriptive statistics and appropriate inferential tests, while qualitative responses underwent thematic analysis. Potential biases, such as sampling and response biases were acknowledged and mitigated as much as possible. The study was approved by the ethical committee of the institution and on official consent was also given for the purpose of performing study. It was certified by the institutional Ethics Committee and approved the proposal of the study as per letter no: KAS:ADM: IEC:0109J:23 approved on 27th November 2023.

A structured questionnaire, which was divided into sections assessing knowledge, attitudes and practices related to materiovigilance, was developed by M Pharm research scholars, department of Pharmacy practice and the questionnaire was developed based on an extensive literature review and expert consultations to ensure comprehensive coverage of the relevant domains. A preliminary validation of the questionnaire was conducted by a pilot study with a sample of 10 healthcare professionals. While their participation ensured content relevance, their data was excluded from the final analysis to maintain the integrity of the primary study. The validation of the KAP (Knowledge, Attitudes and Practices) questionnaire on materiovigilance was conducted using a structured validation tool. Content validation was performed by an expert panel comprising professionals in materiovigilance and healthcare, who evaluated each item for relevance, clarity and comprehensiveness. The Content Validity Index (CVI) was calculated and items that met the threshold were retained. Face validation was then conducted through pre-testing with a small sample of healthcare professionals, leading to further refinement of the questionnaire based on their feedback. During the validation process of the questionnaire, certain limitations were noted, such as the potential for missing dimensions related to specific aspects of knowledge, attitudes, or practices. While the questionnaire comprehensively covered general themes, it might not have fully addressed more nuanced areas, such as detailed procedural knowledge or specific challenges encountered by diverse professional groups. To mitigate these limitations, expert feedback was incorporated to refine the content, ensuring broader representation of essential dimensions. Pilot testing was also conducted to identify gaps and adjust the questionnaire accordingly, thereby enhancing its overall reliability and scope for assessing participants' perspectives on materiovigilance.

Following the validation process, the questionnaire was finalized by revising or removing items that did not meet the required criteria. Ethical approval was obtained for the validation study and informed consent was secured from all participants, ensuring confidentiality and anonymity. The validated questionnaire was then prepared for use in the main study, with the validation process meticulously documented to ensure the tool's credibility.

The questionnaire had a total of four sections. The first section comprised of demographics of participants, this section collects background information including name, profession, qualification, years of experience and present designation through open-ended questions. The second section focused on assessing participants' knowledge of materiovigilance and medical device adverse event reporting. It included 11 questions that covered basic concepts related to materiovigilance, using closed-ended questions and 6 “YES” or “NO” questions to evaluate the participants' understanding. The knowledge aspect of materiovigilance was evaluated through 5 multiple-choice questions, with participants receiving a score of “1” for each correct response and “0” for incorrect answers. Knowledge levels were classified as "satisfactory," "unsatisfactory," or "poor" based on scores from questionnaire, where each response was assigned a numerical value and cumulative scores determined knowledge categories. "Satisfactory" indicated a comprehensive understanding of materiovigilance, encompassing key concepts, reporting protocols and practices. "Unsatisfactory" reflected partial knowledge with notable gaps, showing that while some understanding was present, it was not complete. "Poor" indicated minimal or insufficient knowledge, showing limited awareness of essential procedures or practices. These thresholds were set to evaluate the overall grasp of materiovigilance among healthcare professionals. Altering these scoring boundaries could influence the conclusions by changing the proportion of participants within each knowledge category and thereby impacting interpretations regarding the distribution of understanding among different professional groups. The 3rd section contained 11 questions about the attitude, this section evaluates participants' attitudes towards the topic of interest and answers were recorded. The section including 5-point Likert scale with the options "Strongly agree," "Agree," "Neutral," "Disagree," and "Strongly disagree". The final section assessed participants' practices related to materiovigilance, consisting of 10 close-ended questions, participants had to select the response from “YES” or “NO”. This section explored the participants' current practices concerning the topic, with their responses systematically recorded.

Data collection was conducted over a three-month period utilizing a web-based survey instrument developed on Google Forms. The survey was distributed to participants via WhatsApp and email. To ensure data quality, duplicate entries identified from the same participant and incomplete submissions were excluded from further analysis.

The collected data were summarized by using the Descriptive Statistics: frequency, percentage; mean and S.D. The Pearson correlation coefficient ("r") was used to find the relation between knowledge, attitude and practices about materiovigilance and medical device adverse event reporting. The Likelihood ratio test was used to find the association of knowledge, attitude and practices with profession and years of experience. The p value <0.05 was considered as significant. Data were analyzed by using the SPSS software (SPSS Inc.; Chicago, IL) version 29.0.10.

RESULTS

The questionnaire was distributed to a sample of 700 participants. Of these, 600 respondents provided complete responses, yielding a response rate of approximately 86%. Majority of the respondents were nurses, comprising 43% of the sample (n=255), (41%) n=243 were students, (5.8%) n=35 were dentists, (5.2%) n=31 were pharmacists, (2.2%) n=13 were academicians, (1.2%) n=7 were biomedical engineers, (0.5%) n=3 were optometrists and (1.7%) n=10 were other healthcare professionals (Table 1). The years of experience among respondents were as follows: 522 (87%) had 5 years or below, 34 (5.7%) had 6 to 10 years, 21 (3.5%) had 11 to 15 years, 11 (1.8%) had 16 to 20 years and 12 (2%) had over 20 years of experience (Figure 1).

The Likelihood ratio test was used to find the association of knowledge about materiovigilance and medical device adverse event reporting with profession and years of experience. The knowledge was associated (p<0.05) with the profession (Table 2). A significant majority 79.3% (n=476) correctly identified the ongoing program in India for monitoring adverse events and 74.2% (n=445) understood the purpose of a materiovigilance system. Awareness of the Materiovigilance Program of India (MvPI) was 63.7% (n=382), while only 47.3% (n=284) knew how to report an adverse event. High awareness was noted for who can report events (76.3%) and confidence in identifying adverse events (75.3%). A notable 84% expressed the need for further courses on MvPI safety surveillance, indicating a demand for more education raining in this area. Figure 2 summarizes the response of participants toward knowledge-related questions.

About 89.6% (n=538) believe that including materiovigilance in UG/PG curriculums is essential to create awareness among healthcare professionals. Most respondents 88.9% (n=533) also consider reporting adverse events as a crucial part of their responsibilities. Additionally, 90.4% (n=542) agree that materiovigilance activities help improve the quality of medical devices and 88.8% (n=533) recognize its importance for patient safety. However, only 66.1% (n=397) feel there is adequate training available on materiovigilance for healthcare professionals. Notably, 81.8% (n=491) support establishing Medical Device Monitoring Centers (MDMC) and 76.3% (n=458) are confident that action will be taken following the reporting of a single incident to MvPI (Figure 3). The Likelihood ratio test was used to find the association of healthcare professional's attitude towards materiovigilance with profession and years of experience. The attitude was not associated (p>0.05) with the profession as well as years of experience (Table 3).

About 20.2% (n=121) have participated in MvPI sensitization programs, while 82.5% (n=495) expressed willingness to report Medical Device Adverse Events (MDAEs). A significant majority 72.2% (n=433) have not seen the MDAE reporting form prepared by CDSCO and 56.7% (n=339) do not routinely report adverse events related to medical devices. The study indicates that 72.2% of participants were unfamiliar with the Medical Device Adverse Event (MDAE) reporting form, highlighting a significant gap in awareness that could indeed contribute to lower reporting

Table 1: Demographic characters of the study participants.

(n=600)		Frequency	%
Profession	Academician	13	2.2
	Biomedical engineer	7	1.2
	Dentist	35	5.8
	Nurse	255	42.5
	Pharmacist	31	5.2
	Physician	3	0.5
	Optometrist	3	0.5
	Student	243	40.5
	Other healthcare professionals	10	1.7
Years of experience	5 or below	522	87
	6 to 10	34	5.7
	11 to 15	21	3.5
	16 to 20	11	1.8
	20 or above	12	2

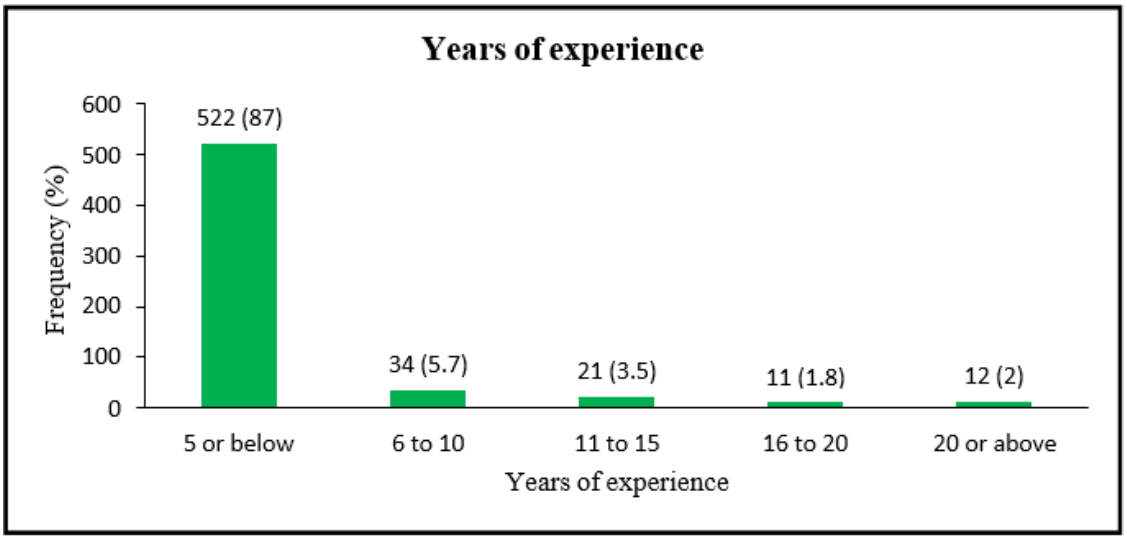

Figure 1: Years of experience of healthcare professionals.

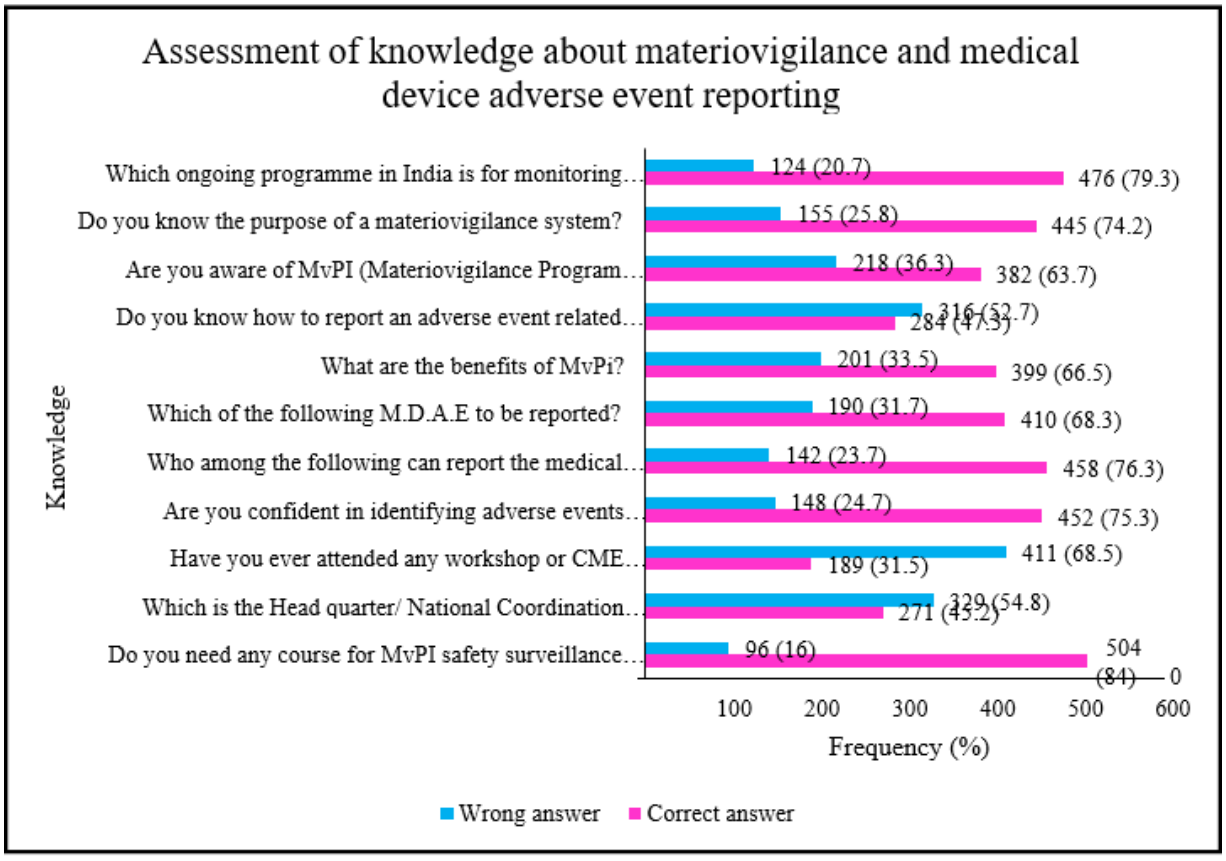

Figure 2: Participants knowledge about materiovigilance.

practices. To address this issue, recommended implementing targeted educational initiatives aimed at increasing familiarity with the MDAE reporting process. This could include training sessions, workshops and informational materials distributed within healthcare settings to ensure all professionals are aware of the form and the importance of reporting adverse events. Additionally, integrating discussions about MDAE reporting into regular professional development and onboarding programs for new staff could foster a culture of safety and accountability. By enhancing familiarity with the reporting process, believe that healthcare professionals will be more likely to engage in proactive reporting practices, ultimately improving the overall safety and monitoring of medical devices. Encouragingly, 88.2% are willing to undergo additional training and 84.2% (n=505) are satisfied with the feedback and follow-up after reporting an adverse event. These findings highlight the need for enhanced training and awareness

Table 2: Association of knowledge about materiovigilance and medical device adverse event reporting with profession and years of experience.

		Knowledge						Likelihood ratio	*p* value
		Poor (< 4)		Unsatisfactory (4-7)		Satisfactory (> 7)			
		n	%	n	%	n	%		
Profession	Academician	1	2.6	4	1.5	8	2.8	32.97	0.007*
	Biomedical engineer	0	0	2	0.7	5	1.7		
	Dentist	0	0	13	4.7	22	7.6		
	Nurse	23	0	133	48.5	99	34.4		
	Pharmacist	2	5.3	11	4.0	18	6.3		
	Physician	0	0	0	0	3	1.0		
	Optometrist	0	0	2	0.7	1	0.3		
	Student	10	26.3	107	39.1	126	43.8		
	Other healthcare professionals	2	5.3	2	0.7	6	2.1		
Years of experience	5 or below	36	94.7	243	88.7	243	84.4	10.38	0.240
	6 to 10	0	0	16	5.8	18	6.3		
	11 to 15	1	2.6	7	2.6	13	4.5		
	16 to 20	0	0	3	1.1	8	2.8		
	20 or above	1	2.6	5	1.8	6	2.1		

(* Significant).

Table 3: Association of healthcare professional's attitude towards materiovigilance with profession and years of experience.

		Attitude				Likelihood ratio	*p* value
		Unsatisfactory (19-37)		Satisfactory (> 37)			
		n	%	n	%		
Profession	Academician	0	0	13	2.3	7.562	0.477
	Biomedical engineer	0	0	7	1.3		
	Dentist	1	0	34	6.1		
	Nurse	20	43.5	235	42.4		
	Pharmacist	2	4.3	29	5.2		
	Physician	0	0	3	0.5		
	Optometrist	0	0	3	0.5		
	Student	21	45.7	222	40.1		
	Other healthcare professionals	2	4.3	8	1.4		
Years of experience	5 or below	44	95.7	478	86.3	5.75	0.219
	6 to 10	1	2.2	33	6.0		
	11 to 15	1	2.2	20	3.6		
	16 to 20	0	0	11	2.0		
	20 or above	0	0	12	2.2		

Table 4: Association of practice of participants regarding materiovigilance and adverse event reporting with profession and years of experience.

		Practices						Likelihood ratio	*p* value
		Poor (< 4)		Unsatisfactory (4-7)		Satisfactory (> 7)			
		n	%	n	%	n	%		
Profession	Academician	1	1.2	8	2.3	4	2.5	146.68	< 0.001*
	Biomedical engineer	1	1.2	2	0.6	4	2.5		
	Dentist	6	7.0	28	7.9	1	0.6		
	Nurse	23	26.7	107	30.3	125	77.6		
	Pharmacist	10	11.6	14	4.0	7	4.3		
	Physician	1	1.2	2	0.6	0	0		
	Optometrist	1	1.2	2	0.6	0	0		
	Student	41	47.7	184	52.1	18	11.2		
	Other healthcare professionals	2	2.3	6	1.7	2	1.2		
Years of experience	5 or below	77	89.5	329	93.2	116	72.0	46.96	< 0.001*
	6 to 10	4	4.7	11	3.1	19	11.8		
	11 to 15	2	2.3	4	1.1	15	9.3		
	16 to 20	0	0	5	1.4	6	3.7		
	20 or above	3	3.5	4	1.1	5	3.1		

(*Significant).

Table 5: Relation between knowledge, attitude and practices.

		Knowledge	Attitude	Practice
Knowledge	"r"	1	0.346	0.217
	p value	--	< 0.001*	< 0.001*
Attitude	"r"		1	0.126
	p value		--	0.002*
Practice	"r"			1
	p value			--

("r"=Pearson correlation coefficient; * Significant).

Table 6: Cumulative scores of knowledges, attitude and practices.

	Range	Mean	S.D.
Knowledge	1 to 11	7.12	2.08
Attitude	26 to 55	45.72	5.50
Practice	0 to 10	5.82	2.44

programs to improve reporting practices and knowledge of materiovigilance among healthcare professionals (Figure 4). The Likelihood ratio test was used to find the association of practices of participants regarding materiovigilance and adverse event reporting with profession and years of experience. The practices were associated (p<0.05) with profession and years of experience (Table 4).

It is clear from Tables 3 and 4 that profession and years of experience is not associated with attitude towards materiovigilance, however, knowledge of materiovigilance has positive association with profession of the individual (p value-0.007). Similarly, materiovigilance practice is positively correlated with profession (p<0.001) and years of experience (p value<0.001). The Pearson correlation coefficient ("r") was used to find the relation between knowledge, attitude and practices. The knowledge, attitude and practices were positively correlated (p<0.05) with each other (Table 5).

Data presents the cumulative scores for knowledge, attitude and practices related to materiovigilance among the participants. The knowledge scores ranged from 1 to 11, with a mean score of 7.12 and a standard deviation of 2.08, indicating a moderate level of knowledge with some variability among respondents. The attitude scores, ranging from 26 to 55, had a higher mean score of 45.72 and a standard deviation of 5.50, suggesting generally positive attitudes towards materiovigilance, though with notable differences in individual perspectives. The practice scores ranged from 0 to 10, with a mean of 5.82 and a standard deviation of 2.44, reflecting varying degrees of engagement in materiovigilance practices, with some participants more actively involved than others. This data underscores the diverse levels of knowledge, attitudes and practices among the participants, highlighting areas for potential improvement in materiovigilance education and practice (Table 6).

The data indicates that the majority of healthcare professionals had satisfactory knowledge (48%) *n*=288 regarding materiovigilance, though a significant portion (45.7%) *n*=274 had unsatisfactory knowledge and (6.3%) *n*=38 had poor knowledge. Attitudes towards materiovigilance were overwhelmingly satisfactory, with 92.3% (*n*=554) demonstrating a positive attitude, while 7.7% (*n*=46) were unsatisfactory. In terms of practices, 26.8% (*n*=161) were satisfactory, 58.8% (*n*=353) were unsatisfactory and 14.3% (*n*=86) were poor (Table 7). Statistical analysis revealed that knowledge and practices were significantly associated ($p<0.05$), whereas attitude was not significantly associated ($p>0.05$). The positive attitudes dominating at 92.3% reflected strong support for the importance of materiovigilance, emphasizing a shared commitment to patient safety and proactive reporting practices. Analysis showed that healthcare professionals, regardless of job group, valued the benefits of adverse event reporting; however, subtle differences emerged. For instance, doctors and pharmacists often expressed greater confidence in existing reporting frameworks due to their direct involvement, while engineers highlighted the technical significance of device monitoring. Experience level also played a role: seasoned professionals demonstrated a deeper understanding and adherence to materiovigilance protocols, whereas newer staff brought fresh enthusiasm but required more awareness-building to match the same level of confidence. This suggests that while healthcare professionals generally have a positive attitude towards materiovigilance, there is a need for improvement in knowledge and practices to enhance the overall effectiveness of the program (Table 7).

DISCUSSION

Medical devices are critical to patient care but can also present safety risks. Consequently, robust surveillance systems are essential to identify and mitigate adverse events associated with their use. However, a significant challenge in optimizing medical device safety is the underreporting of adverse incidents, hindering comprehensive risk assessment and timely intervention.[7] While extensive research has explored healthcare professionals' Knowledge, Attitudes and Practices (KAP) regarding pharmacovigilance, comparable investigations into materiovigilance are notably scarce.[8] Therefore, this study was conducted among various healthcare professionals, who regularly use various medical devices for diagnostic and therapeutic purposes in their patients. Effective medical device surveillance is crucial for patient safety and healthcare quality. Enhancing knowledge and practice of Medical Device Adverse Event (MDAE) reporting among healthcare providers is a primary goal of the MvPI initiative. Given the documented knowledge gaps and suboptimal reporting practices among healthcare professionals in other regions, this study aimed to assess the Knowledge, Attitude and Practice (KAP) of materiovigilance among healthcare professionals of various settings.[9]

While most professionals agree to the lack of knowledge and established practices and knowledge gap to practicing optimal materiovigilance, a majority of them emphasise the need for programs that impart knowledge in order to improve medical device safety among patients. This asserts a high level of positive attitude among professionals towards materiovigilance programs, however, lack of knowledge and established practices act as a bias to practicing safe materiovigilance, which implies the need for structured materiovigilance programs along with adequate education and trainings for the professionals. To enhance the

Table 7: Grading for knowledge, attitude and practices.

		Frequency	%
Knowledge	Poor (< 4)	38	6.3
	Unsatisfactory (4-7)	274	45.7
	Satisfactory (> 7)	288	48
Attitude	Unsatisfactory (19-37)	46	7.7
	Satisfactory (> 37)	554	92.3
Practice	Poor (< 4)	86	14.3
	Unsatisfactory (4-7)	353	58.8
	Satisfactory (> 7)	161	26.8

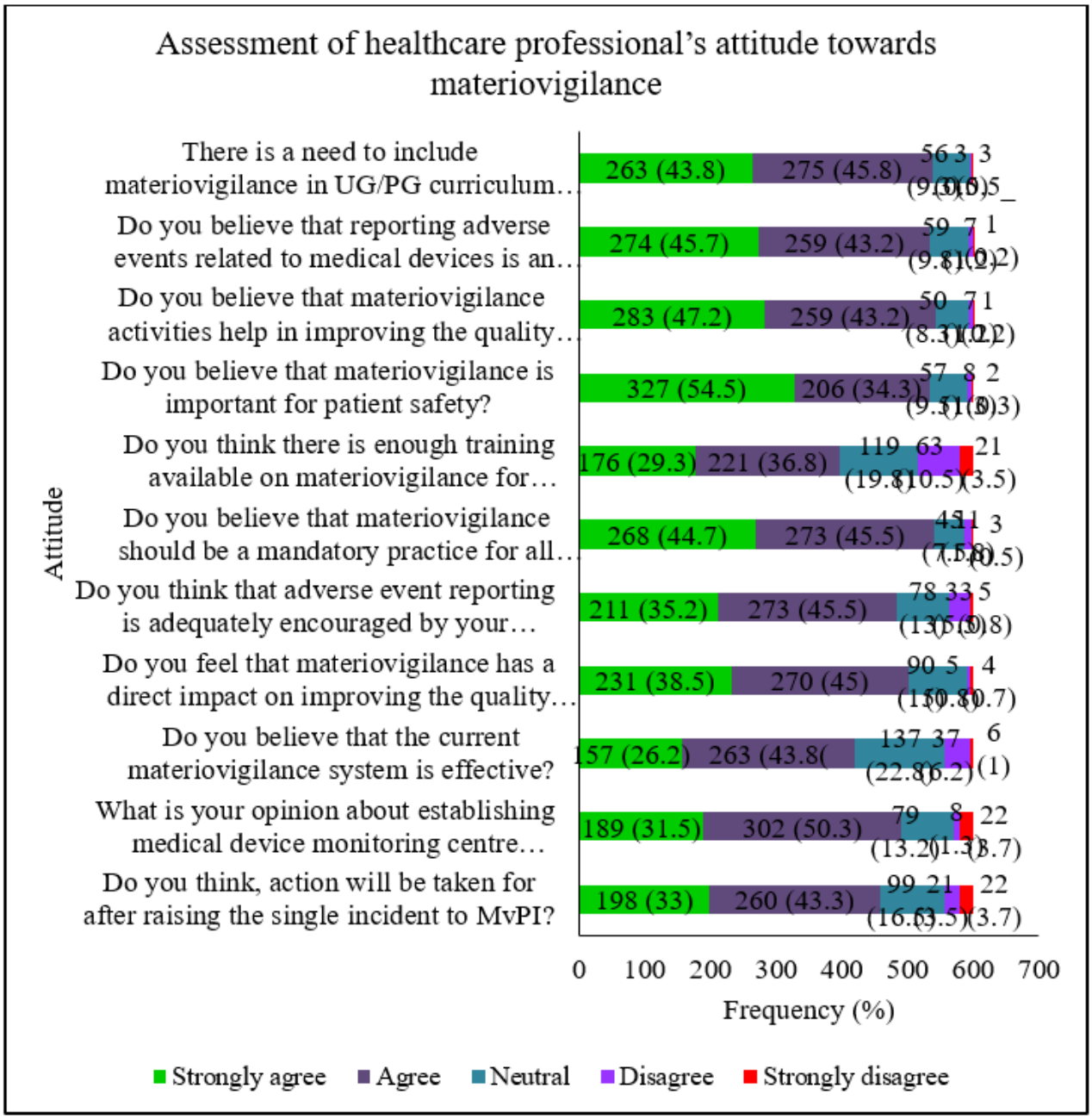

Figure 3: Participants attitude about materiovigilance.

relevance of the study across the entire healthcare professional community, it is important to acknowledge that the substantial representation of nurses and students in the sample provides valuable insights into the perspectives of these critical roles. While these groups may have distinct experiences and attitudes shaped by their specific functions and levels of training, this diversity can enrich our understanding of materiovigilance, shaped by their specific roles and levels of training. For instance, nurses often engage directly with patient care and may prioritize reporting practices differently than physicians or pharmacists, who may have more complex decision-making responsibilities regarding device use and patient safety. This disparity could result in findings that are more reflective of the viewpoints of less experienced professionals, potentially overlooking critical insights from those with greater expertise or different roles. To enhance the study's relevance across all healthcare professionals, highlight this limitation and recommend strategies for future research that include a more balanced representation of various professional groups, ensuring a more holistic understanding of attitudes toward materiovigilance.

The study achieved an exceptionally high response rate, significantly surpassing those reported in previous research by Meher *et al.*, Alsohime F *et al* and Aida K *et al.*[1,10,11] A substantial majority of participants in this study 88.9% (*n*=533) exhibited a positive disposition towards MDAE reporting. This finding

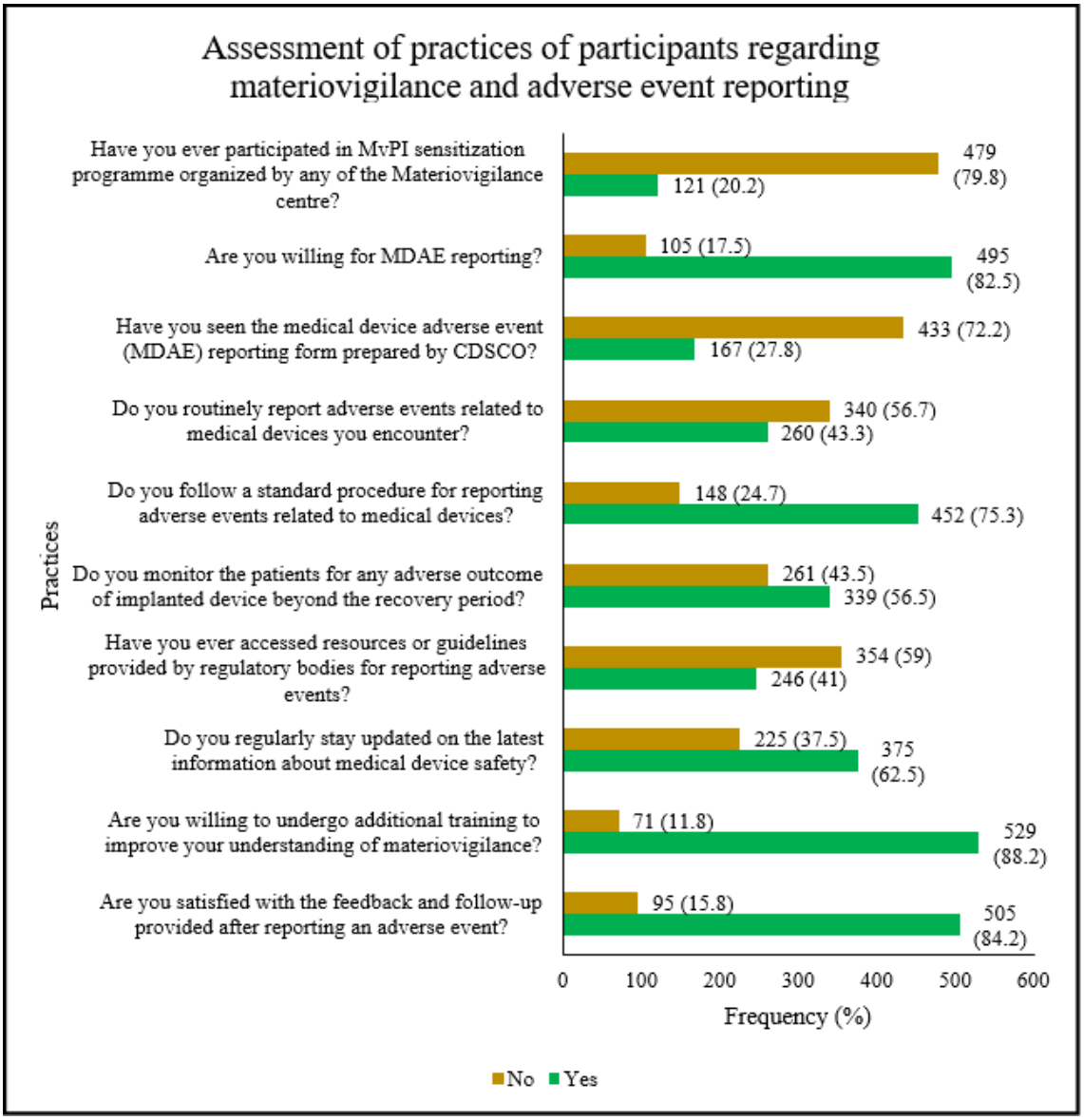

Figure 4: Participants practice about materiovigilance.

aligns with the consistent results reported by Mohamed et al. and Meher *et al.* in their respective investigations.[1,12] Shukla *et al.* (2020) recommended incorporating education and reporting guidelines for Medical Device Adverse Events (MDAEs) into the undergraduate and postgraduate curricula for healthcare professionals.[13]

The study revealed a significant knowledge gap among medical professionals regarding materiovigilance. Many participants demonstrated limited awareness of the recently implemented MvPI framework established by the Ministry of Health and Family Welfare (MoHFW), Government of India to monitor Medical Device Adverse Events (MDAEs) which were similarly observed in a study conducted by Nabi *et al.*[6] Furthermore, a substantial proportion of respondents expressed uncertainty about the appropriate reporting channels for MDAEs. These findings suggest that materiovigilance has not yet achieved the same level of recognition and engagement within the medical community as pharmacovigilance. A comparable observation was made in a Romanian study conducted by Mirel *et al.*[14]

Comparing the total KAP (Knowledge, Attitude and Practice) scores based on years of work experience, nurses significantly outperformed other participants. This higher score could be attributed to their greater exposure to MDAEs in patients, more active involvement in patient management and the preventive measures they undertake against MDAEs compared to other

healthcare professionals, Consistent findings were reported in studies conducted by Sivagourounadin K *et al.*[9] In some study participants exhibited significantly poor practices regarding adverse event reporting. A considerable number had neither participated in any training programs on adverse event reporting nor submitted any adverse event reports. This deficiency likely stems from a lack of awareness and an inadequate reporting

system. Gagliardi *et al.* identified several barriers to effective materiovigilance among medical professionals, including insufficient reporting systems and the lack of a supportive environment.[15] We hypothesize that reporting culture among medical professionals can be enhanced through interventions such as continuous medical education, workshops and other training programs. A study conducted by Coyle *et al.* demonstrated that early exposure of postgraduate medical trainees to medical event reporting education programs positively influenced their attitudes towards reporting.[16] A systemic problem within vigilance programs has been found to be under reporting.[17] Many professionals recognize the importance of AE reporting but lack the necessary knowledge or understanding of how to report, what to report, or the impact of their reports. This knowledge deficit hinders their ability to effectively contribute to device safety.[18]

It strengthens, the study had a great impact on the knowledge, attitude and practice of the healthcare professionals, which will we believe in the future help them to contribute more towards monitoring and reporting of medical device adverse events. From this study we can introduce the concept of materiovigilance, helping them become familiar with this new concept and highlights the necessity of mandatory reporting by healthcare professionals, manufactures and biomedical engineers. These strengths collectively enhance the overall safety and effectiveness of medical devices in clinical practice. Integrating knowledge-based platforms that combine disease, gene and pharmacological information can enhance healthcare practitioners' expertise in adverse event reporting. These platforms can provide comprehensive resources linking medical devices to associated adverse events and pharmacogenomic data, helping professionals recognize potential issues more effectively. Additionally, interactive modules and real-time reporting tools can foster engagement and build confidence in reporting practices. Ultimately, these resources could lead to improved patient safety and more effective materiovigilance initiatives.

While the results are promising, there are a few limitations to consider. The major reasons for under-reporting of MDAEs were due to lack of knowledge about the reporting procedure, unavailability of the reporting centers, unavailability of the MDAE report form, lack of knowledge of the existence of a national MDAE reporting system and belief that the adverse events in question was already well known, events were not serious, uncertainty concerning the causal relationship between the adverse events and the device, forgetting to report the MDAEs and lack of time and ignorance of reporting procedure.[19]

CONCLUSION

The current study reveals that medical professionals with sufficient knowledge of materiovigilance also exhibit a positive attitude toward reporting Medical Device Adverse Events (MDAEs). Notably, most of the healthcare professionals were unaware of the current Materiovigilance Program of India (MvPI). Consequently, it can be concluded that while knowledge and practice of materiovigilance among medical professionals in various healthcare facilities are inadequate, their positive attitude towards adverse event reporting is encouraging. This positive attitude indicates that with proper guidance, these professionals can be motivated to participate in Continuing Medical Education (CME), hands-on training and awareness programs focused on Adverse Drug Reaction (ADR) monitoring and reporting. Such initiatives will foster better reporting practices and help disseminate materiovigilance knowledge among their peers. Additionally, expanding existing ADR monitoring centers to include MDAE reporting will be crucial in achieving the goals of the Materiovigilance program.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

MvPI: Materiovigilance Programme of India; **MDAE:** Medical Device-Associated Adverse Event; **KAP:** Knowledge, Attitudes and Practices; **HCP:** Healthcare Professional; **AE:** Adverse Event.

SUMMARY

A prospective observational study was conducted at KIMS Al-Shifa Super Specialty Hospital in Kerala, India, to assess the Knowledge, Attitudes and Practices (KAP) of healthcare professionals concerning materiovigilance and medical device adverse event reporting. The study included 600 randomly selected participants, encompassing a diverse group of healthcare professionals, including physicians, pharmacists, nurses and others. Data were gathered through a combination of online surveys and face-to-face interviews and were subsequently analyzed using descriptive statistics and inferential tests. The findings indicated that, although the majority of participants exhibited a positive attitude towards materiovigilance, there were notable deficiencies in both knowledge and practical application, particularly in the reporting of adverse events. These results underscore the critical need for targeted training and educational initiatives to enhance materiovigilance practices and safeguard patient safety.

Ethics Approval was certified by the institutional Ethics Committee and approved the proposal of the study as per letter no: KAS: ADM: IEC:0109J:23 approved on 27th November 2023.

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