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Original Research Article

Knowledge attitude and practice of materiovigilance among healthcare professionals in tertiary care hospitals

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ABSTRACT

Background: Materiovigilance (Mv) refers to the systematic monitoring and evaluation of medical devices in order to assess their performance and safety during all stages of their life. The purpose of Mv is to identify and avoid any potential hazards or issues linked with medical equipment. In brief, Mv plays an important role in ensuring the performance and safety of medical equipment. It consists of the systematic observation, the collection, and analysis of data on occurrences and adverse events related to medical equipment. The study was conducted to assess knowledge, attitude, and practice regarding Mv among healthcare professionals in tertiary care hospitals.
Methods: Self-prepared and validated questionnaires were distributed among healthcare Professionals in India through online forms from December 2022 to July 2023, a cross-sectional questionnaire-based survey was used, with convenience sampling utilized. Responses from 220 subjects were analyzed.
Results: The primary objective of this study was to assess the demographic details of the Healthcare Professionals as well as the distribution of knowledge, Attitude, Practice on Mv, in a list of 220 responses, 40% of them know about the Mv. Remaining 60% of them they don't know about the Mv. Total 220 responses, 76.8% of the Healthcare professionals suggested to thought about the Mv, remaining 23.1% were disagreed. 75 out of 220 healthcare professionals acknowledged to seeing the reporting form and experiencing AE in their patients, while the remaining 145 denied it.
Conclusions: This study determined the knowledge, attitude and practice of Mv among healthcare professionals in tertiary care hospitals. According to the current study, the majority of healthcare professionals were knowledgeable and supportive of Mv, however they are not as effective in practice.

Keywords: Mv, Medical devices, Medical Equipment, Adverse events

INTRODUCTION

Materiovigilance (Mv) refers to the systematic monitoring and evaluation of medical devices in order to assess their performance and safety during all stages of their life.[1] It is a fundamental aspect of medical device post-market surveillance and assures that patients are safe.[2] The theoretical framework of Mv is similar to that of pharmacovigilance, which is concerned with the safety of drugs. Comparable to how pharmacovigilance needs acquiring, analyzing, and determining data on adverse medication reactions, Mv entails collecting and evaluating information on medical device occurrences, issues, and adverse events.[3,4]

The purpose of Mv is to identify and avoid any potential hazards or issues linked with medical equipment.[2] Regulatory bodies, vendors, and health care providers can gather data on incidents and adverse events to identify patterns or trends that may indicate possible safety or

performance problems with certain medical devices.[5] Using this information, relevant actions such as sending safety alerts, conducting product recalls, or modifying regulatory rules can then be taken.[1] Healthcare workers play a significant part in Mv by documenting incidences and adverse events when making use of medical devices. [5] They are asked to notify the appropriate regulatory bodies or vendors of any potential concerns as soon as possible because their feedback contributes to the overall oversight and surveillance process.[6] The European Union (EU) has implemented Mv regulations through the medical devices regulation (MDR) and the In Vitro Diagnostic Devices Regulation (IVDR). These regulations offer a framework for gathering and analyzing data on accidents, issues, and adverse occurrences regarding medical devices sold in the EU. Such rules and regulations exist in other countries, notably the United States (FDA's post-market surveillance system) and Canada (Mv Programme).[7,3] In brief, Mv plays an important role in ensuring the performance and safety of medical equipment. It consists of the systematic observation, the collection, and analysis of data on occurrences and adverse events related to medical equipment.[8] Material vigilance contributes to improved patient safety in healthcare settings by proactively identifying and addressing potential hazards and concerns.[5] Mv is an important subject which concentrates on continuous surveillance and monitoring of medical devices to ensure their dependability and efficacy. Material vigilance, like pharmacovigilance, serves as essential for post-market monitoring and risk management of medical devices.[6,8]

The primary purpose of Mv is to identify and avoid any potential hazards or difficulties associated with medical equipment. By collecting and analyzing data on events, failures, and adverse occurrences, regulatory authorities, manufacturers, and healthcare professionals can identify developments or patterns that may indicate safety or performance difficulties. With this information, right away actions to preserve patient safety, such as product recalls, regulatory rules revisions, or safety alerts, can be carried out.[9] Mv mechanisms have been created at the national and international levels to ensure a comprehensive approach to device safety. Regulatory agencies enforce regulation compliance while also supervising Mv operations. Healthcare professionals must report any suspected difficulties they encounter while using a device, and manufacturers are required to publish occurrences and adverse events connected to their medical devices.[3,4] The European Union implemented Mv regulations through the MDR and the IVDR. These regulations provide a framework for gathering, examining, and spreading information about medical device incidents and unfavourable outcomes. Other regions, such as the United States and Canada, have their own Mv systems in place to ensure the safety of medical equipment across their borders.[10] Mv is a continuing process designed to encourage stakeholder cooperation, accountability, and open communication. It promotes a proactive approach to risk management and aids in raising patient safety standards within healthcare facilities. We can ensure that medical devices perform their intended purpose and enhance patient care by being vigilant and taking care of potential issues as soon as they arise. Remember to alert the appropriate regulatory bodies or manufacturers if you have any concerns or issues with medical devices. Your active involvement in Mv contributes to the safety and well-being of patients all over the world.[11,12] Mv refers to a range of surveillance and monitoring practices with the goal of guaranteeing the functionality and safety of medical devices. The functions that these various Mv modalities play in identifying and controlling the dangers connected to medical devices are complimentary.[1,2] Some of the main categories of Mv are as follows:

Spontaneous reporting

In this type of Mv, health care providers, patients, or others report incidents, issues, or adverse events related to medical devices freely. Individuals must take the initiative to report any suspected faults they encounter while using a device if spontaneous reporting is to occur. Regulatory agencies generally ask medical device makers to disclose occurrences, problems, and adverse events related to their devices. This type of Mv holds manufacturers accountable for tracking and evaluating the performance and safety of their products throughout their lifecycles.[13]

Reporting by user facilities

User Facilities, such as hospitals or clinics, play an important role in Mv by documenting occurrences, problems, and adverse events involving medical equipment utilized on their premises. These studies provide useful information about how gadgets work and potential hazards in real-world healthcare settings.[14]

Periodic safety update reporting (PSUR)

PSUR is a methodical gathering and assessment of safety-relevant data regarding medical equipment. Manufacturers are usually responsible for providing to regulatory bodies periodic safety reports that update the safety profile of their products based on available data and analysis.[15]

Post-market clinical follow-up (PMCF)

PMCF refers to the collection of clinical data on medical devices after they have been publicly released. This type of Mv attempts to collect data on the long-term performance and safety of devices in practical problems patient populations, assisting in the identification of any potential hazards or problems that could occur over time. [13,14]

Post-market surveillance studies

Post-market surveillance studies are carried out in order to evaluate the performance and security of medical devices in everyday situations. These studies may include large-

scale data collection, analysis of unfavourable outcomes, or evaluation of device performance in specific patient populations.[12,13]

Mv activities entail global collaboration and information sharing among manufacturers, regulatory bodies, and healthcare practitioners. Sharing data, best practices, and lessons learnt helps to advance worldwide efforts to improve patient care while also furthering our understanding of device safety in general.[2,7] By combining these various types of Mv, stakeholders can efficiently monitor, assess, and control the performance and safety of medical devices throughout their lives. This all-encompassing technique improves patient outcomes while also promoting medical device safety.[5,9] Since there are currently few studies on the awareness of Mv, this research has been undertaken in order to investigate the knowledge and attitude towards Mv among doctors at a tertiary care hospital.

METHODS

A cross-sectional observational study was conducted among healthcare professionals in tertiary care hospitals. This study involves to know their knowledge, practice and attitude and practice of Mv among Healthcare professionals and their importance. The Study was conducted from the period of February 2023 to June 2023. The Study duration is from December 2022 to July 2023 and the Study site is Sri. Ramachandra hospital, G-block and Udayar block.

Written informed consent form was obtained from each participant before enrolment. The study was conducted using self-framed and validated KAP questionnaires among healthcare professionals and then collected data were analyzed. The sample size was determined by using n master software. The sample size required for this study would be 220. The Inclusion criteria are Healthcare Professionals who are willing to participate. The exclusion criteria are healthcare professionals unwilling to give inform consent, Medical Students, Biomedical engineers, Patients. and the data collection procedure are Self-administered questionnaire (Permission Questionnaire) will be used for the data collection. The collected data were analysed by t-test, p value with IBM, SPSS statistic software 60.0. To describe about the data, descriptive statistical frequency analysis, and percentage analysis categorical variables were used.

Statistical methods

The collected data were analysed with IBM SPSS statistic software 16.0. By using the categorical variables, descriptive statistics, and percentage analysis were found. To find out significant difference between samples chi-square test was used. In the above statistical tool, the probability value <0.05 is considered as significant level.

RESULTS

A total of 220 healthcare professionals from tertiary care hospital were enrolled into the study.

Table 1: Demographic details of the respondents.

Demographic details	N	%
Gender		
Male	144	65.45
Female	76	34.54
Age (years)		
21-25	104	42.27
26-30	35	15.9
31 and above	81	36.8
Educational status		
Doctor	82	37.27
Nurse	99	45
Pharmacist	39	17.72

Table 2: Knowledge wise response

Knowledge	Yes, N (%)	No, N (%)	P value
Do you know Mv?	88 (40)	132 (60)	0.013
Are you aware of any medical device that has been recently banned due to MDAE?	75 (34.09)	145 (65.90)	0.045
Do you know about MDAE in your hospital?	75 (34.09)	145 (65.90)	0.001
Are you aware of MDAE reporting in India?	81 (36.81)	139 (63.18)	0.013
Do you know any other Reporting sources?	76 (34.54)	144 (64.45)	0.016

The demographic details were found to be 144 were female and 76 were male out of 220 Healthcare Professionals which shows female respondents higher than male respondents. This survey comprises Healthcare professionals from the age of 21. There were more responses between the ages of 21 and 25 was 104, age between 26 and 30 was 35, age 31 and above was 81. Data collected on the knowledge, attitude, and practice of Mv were gathered from 82 doctors, 99 nurses, and 39 chemists out of 220 responses. Demographic details are characterized in (Table 1). Knowledge wise response is in a list of 220 responses, 40% of them know about the Mv. Remaining 60% of them they don't know about the Mv. 75 respondents out of 220 response they aware about the medical device that has been recently banned due to MDAE. Remaining 145 respondents they didn't aware about that. Out of 220 responses 65% of the people disagreed that they even don't know about the MDAE in hospital where 34% of the people agreed. In a list of 220 response, 81 of the people were aware about the reporting MDAE in India, where remaining 139 of the people they didn't aware about it. Among 220 responses, Majority of

the healthcare professionals haven't knowledge about the any other reporting sources. Knowledge wise response is characterized in (Table 2).

Table 3: Attitude wise response

Attitude	Yes, N (%)	No, N (%)	P value
Do you think Mv should be taught in detail to Health Care Professionals?	169 (76.81)	51 (23.18)	0.133
Do you think reporting of MDAE is necessary?	169 (76.81)	51 (23.18)	0.217
Have you anytime read any article or seen any news on prevention of MDAE?	43 (19.54)	177 (80.45)	0.786
What is your opinion about establishing MDAE reporting center in every hospital?	169 (76.81)	51 (23.18)	0.619

Table 4: Practice wise response

Practice	Yes, N (%)	No, N (%)	P value
Have you ever seen the MDAE reporting form? Have you ever experienced MDAE in your patient during your professional practice?	75 (34.09)	145 (65.90)	0.044
Have you ever been trained on how to report MDAE?	104 (47.27)	116 (52.72)	0.080
Have you ever experienced MDAE in your patient during your professional practice?	74 (33.63)	146 (66.36)	0.026
Have you ever reported a MDAE to the Mv centre?	56 (25.45)	164 (74.54)	0.066
Are you willing to do MDAE reporting?	133 (60.45)	87 (39.54)	0.128
Do you keep records of MDAE as per the norms of the institute policy?	83 (37.72)	137 (62.27)	0.014

Attitude wise response was found to be total 220 responses, 76.8% of the Healthcare professionals suggested to thought about the Mv, remaining 23.1% were disagreed. Among 220 Healthcare Professionals, 169 of the respondents they agreed MDAE is necessary for reporting. Remaining 51 of the respondents were disagreed. 43 healthcare professionals out of the 220 responses agreed that they had already read articles or seen any news on the prevention of MDAE, whereas 177 disagreed. Out of 220 responses, 169 healthcare professionals were given positive responses in favor of establishing MDAE reporting center in every hospital and 51 were given negative responses. Attitude wise response is characterized in (Table 3).

Practice wise response is 75 out of 220 healthcare professionals acknowledged to seeing the reporting form and experiencing AE in their patients, while the remaining 145 denied it. Among the 220 responses, 104 healthcare professionals agreed that they had been trained to report MDAE, while 116 disagreed. 74 healthcare professionals experienced an adverse event (MDAE) in a patient, while 146 disagreed within the 220 responses. Out of 220 individuals who responded, 56 acknowledged that they had reported MDAE to the Mv center, while 164 denied it. Within the 220 responses, 133 healthcare Professionals are willing to report MDAE and 87 are not. Among the 220 responses, 83 healthcare professionals agreed that they kept records in accordance with the norms, whereas 137 disagreed. Practice wise response is characterized in (Table 4).

DISCUSSION

The current study has focused on the knowledge, attitude, and practice of Mv among healthcare professionals in tertiary care hospitals. 220 Healthcare Professionals answered KAP questionnaires that were distributed. All of them agreed to participate in our study, and they all answered our questionnaire. The percentage of healthcare professionals who took part in the study showed were significantly more female (65.45%) participants than male (34.54%). The results of the investigations done by Sivagourounadin K et al could give credibility to this.[16] When respondents answered about Mv, 60% of the study participants does not know about Mv, which is in line with the findings of Sivagourounadin et al.[16] The majority of healthcare professionals (65.90%) does not aware of any medical device that has been banned recently due to MDAE which is similar to the study of Sivagourounadin et al.[16] According to Indushree et al healthcare professionals (63.18%) does not aware of MDAE reporting in India which is similar to our study.[17] Indushree et al conducted a questionnaire study on a KAP of Mv which is similar to our study with majority of healthcare professionals (19.54%) embraced reading any articles or watching any news about preventing MDAE.[17] According to Sivagourounadin et al healthcare professionals (76.81%) accepted that Mv should be taught in detail to healthcare professionals which is similar to our study.[16] The majority of healthcare professionals (76.81%) agreed that it is important to report medical device adverse event (MDAE) which is similar to the study of Meher et al.[18] In this study, about 76.81% of healthcare professionals gave some opinion about establishing MDAE reporting centers in every hospital; this is concordant with KAP of Mv study carried out by Indushree et al.[17] Similar to Sivagourounadin et al the majority of healthcare

professionals (65.90%) disagreed with the question, "Have you ever experienced MDAE during your professional practice.[16] In this study, about (52.72%) of healthcare professionals gave disagreed to the question, “Have you been trained on how to report MDAE” which is similar to KAP of Mv study carried out by Sivagourounadin et al. [16]

Similar to Meher et al, the majority of healthcare professionals (66.36) disagreed with the question, "Have you ever experienced MDAE in your patient during your professional practice. "Comparable to Meher et al 60.45% of healthcare professionals in this survey indicated that they would be willing to reporting MDAEs.[18] About (62.27%) of the healthcare professionals in this study disagreed to keep an ADR record, which is similar to the KAP of Mv Sivagourounadin et al.[16] Hence, we consider it as a fair knowledge among Healthcare Professionals. This study determined the knowledge, attitude and practice of Mv among healthcare Professionals in Tertiary care hospitals. According to the current study, the majority of Healthcare Professionals were knowledgeable and supportive of Mv, however they are not as effective in practice. In view of the previously stated, actions are required to instruct, empower, and train Healthcare Professionals in the field of Mv.

CONCLUSION

This study determined the knowledge, attitude and practice of Mv among healthcare professionals in tertiary care hospitals. According to the current study, the majority of healthcare professionals were knowledgeable and supportive of Mv, however they are not as effective in practice.

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