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Original Research Article

KNOWLEDGE, ATTITUDE AND PRACTICES OF MATERIOVIGILANCE AMONG THE MEDICAL PROFESSIONALS IN A TERTIARY CARE CENTRE: A CROSS-SECTIONAL STUDY

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Abstract

Background: The safety of patient care is of utmost importance, and with the rise in reported medical device-related adverse events it has become clear that healthcare professionals must understand the concept of Materiovigilance. To gain insight into their current knowledge, attitude, and practice regarding this matter, we conducted a study at a tertiary teaching hospital.. **Materials and Methods:** It was a descriptive, cross-sectional study conducted among medical professionals using a self-administered, validated questionnaire. The questionnaire was distributed to 252 medical professionals and descriptive and inferential statistical analysis has been carried out to analyse the results. **Result:** The findings in the study suggest that many healthcare professionals are aware of this risk, but gaps remain. Out of 252 responses from healthcare professionals, it was found that 52% were aware of MVPI (Materiovigilance programme of India) and 94.8% believed it should be mandatory to report any adverse events related to medical devices. Unfortunately, only 10.3% had reported such an event. **Conclusion:** The implementation of the Materiovigilance programme of India (MvPI) is a critical step to ensure the quality and safety of medical devices. Our study results have highlighted the need for greater awareness of Materiovigilance among health care professionals and stronger enforcement measures to effectively implement the programme.

INTRODUCTION

The healthcare industry relies on medical devices to ensure quality of life and provide the best possible care for patients. From sophisticated computerized equipment to basic instruments, these devices play a key role in our healthcare system.[1] However, due to malfunction or defects, serious incidents such as electrical burns and particles in blood may occur. To mitigate this risk, there must be a proper system in place to maintain the standard and safety of medical devices–and this is where Materiovigilance comes into play. Materiovigilance encompasses the close monitoring, collection and assessment of safety data related to medical devices.[2]

In 1970, the United States took a leap forward in post-market surveillance of medical devices by passing the Food and Drug Administration (FDA) Modernization Act under Section 522 which established a rigorous process for monitoring and regulating medical devices.[2-4] Now India is joining the movement with its own Medical Device Materiovigilance Programme (MvPI). Launched on July 6, 2015, at the Indian Pharmacopoeia Commission (IPC), Ghaziabad by the Drugs Controller General India Since then, CDSCO has been tasked with regulating medical devices in India under the umbrella of the Ministry of Health and Family Welfare for the Government of India. As part of its implementation plan, Sree Chitra Thirunal Institute of Medical Sciences & Technology (SCTIMST), located in Thiruvananthapuram provides valuable support to this program by serving as a National Collaborating Centre for MvPI. On May 4th, 2022, Indian Pharmacopoeia Commission launched an aggressive implementation plan across all districts in Kerala to facilitate effective tracking and monitoring of adverse events due to medical devices, while also focusing on their benefit-risk profiles along with raising awareness among healthcare professionals

Rationale of the Study

The safety of medical devices is critical for the success of patient care. To better understand and assess the knowledge, attitude and practice of health

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professionals regarding Materiovigilance, we are conducting a study in a tertiary care teaching hospital. Health professionals play a vital role in Materiovigilance as they report any adverse events related to medical devices. Evidence suggests that there is a significant lack of knowledge regarding Materiovigilance amongst medical professionals.[3,5] Therefore, we believe it is imperative to gauge their understanding so the Materiovigilance programme of India (MVPI) can be implemented successfully. Through this study, we hope to raise awareness on the importance of Materiovigilance among health professionals and ensure its successful implementation.

Objectives

Primary Objective: To evaluate the knowledge, attitude and practice among medical professionals towards Materiovigilance.

MATERIALS AND METHODS

Study design and study setting

This was a descriptive, cross-sectional study with convenient sampling methods for sampling purposes conducted among healthcare professionals working at the Sree Narayana Institute of Medical Sciences in Chalakka, Ernakulam, Kerala.

Inclusion Criteria

Doctors, nurses and OT technicians working in Sree Narayana Institute of Medical sciences who is willing to participate in the study

Exclusion Criteria

- Health care professionals other than doctors' nurses and OT technicians working in Sree Narayana Institute of Medical sciences
- Doctors and nurses not willing to participate in the study
- Those medical professionals who have already participated in the pilot study.

Ethical Approval and Sample Size Calculation

This study was approved by the Institutional Ethics Committee. Taking relative precision as 5% and desired confidence level as 95% the sample size was calculated to be 250(considering non-response rates)

Study tool and data collection

The questionnaire was developed after a literature review of comparable studies 15 itemed structured survey tool (Questionnaire) was designed by faculty members of department of pharmacology.[5,6]

The questionnaire was validated by conducting a pilot study on a sample of 20 medical doctors, who were finally excluded from the study.

The structure of questionnaire comprises of 4 sections

a. Demographic details -Demographic details will be recorded as open-ended questions.
b. Knowledge were presented as closed-ended and open-ended questions and Attitude and Practice section answers were recorded

The participants who met the inclusion criteria were enrolled in the study. We gathered data utilizing Google Forms, distributed through WhatsApp/emails. Duplicate responses from the same participant and incomplete submissions were excluded. This response collection process occurred over a one-month period.

Statistical Methods

Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean, SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5 % level of significance. The following assumption on data is made

Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups, non-parametric setting for Qualitative data analysis. Fisher Exact test used when cell samples are very small.

p value <0.05 will be considered as statistically significant.

RESULTS

Of the 255-questionnaire distributed, a total of 252 health care professionals gave consent to participate in this study and responded to the questionnaire. The demographic details of the healthcare professionals with baseline characteristics are summarized in [Figure 1].

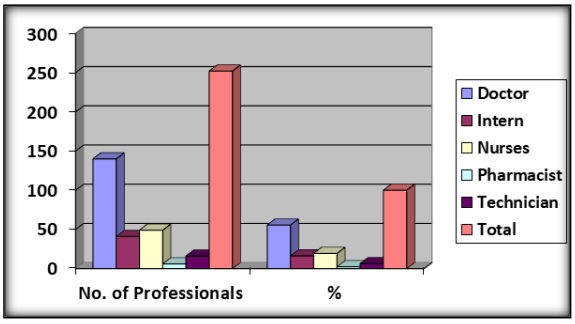

Figure 1: Demographic details of healthcare professionals

Healthcare Professionals Knowledge on Medical Device related Adverse events Reporting

The awareness about ongoing programme in India for monitoring medical device related adverse events were around 52 % among healthcare professionals, which was slightly higher than similar study done by Bikash Ranjan Mehar et al. 57 % of the respondents were aware about the classification of medical devices and majority of them gave correct response regarding the category where bone marrow needle belongs to. 59.5 % has given correct answer for MvPI full form and 88.5% of the respondents were aware the of the importance of reporting of medical device related adverse events. 67.5% of the health care professionals had knowledge about the regulatory body responsible for monitoring medical device related adverse events in India. The results of the present study [Table 1] are slightly higher to

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knowledge when compared with the previous similar studies.[5,7]

Health Professionals Attitude towards Materiovigilance [Table 2]

A total of 99.6% % of the healthcare professionals are conscious that medical devices can cause adverse events and 94.8% of the participants believe that healthcare professionals are owed to report medical device related adverse event. Majority of the participants are of the opinion that establishing medical device related adverse events monitoring centre in every hospital is obligatory and it helps to improve the patient safety. The healthcare professionals participated in this study are certain that Materiovigilance should be educated in detail to the healthcare professionals. The results of questions related to attitude towards Materiovigilance in this study are comparable with the previous similar studies.[6,8]

Health care professional's response towards practice-related questions [Table 4]

Among the participants, 28.2% have encountered medical device related adverse events in their practice, 16.75% have been come across the MDAE reporting form unfortunately 10.3 % had reported adverse event related to medical devices [Table 4].

Table 1: Knowledge of healthcare professionals on Materiovigilance

	Correct Response n=252	Incorrect Response n=252
Mention the ongoing program in India for monitoring adverse events due to medical devices	52%	50%
Medical devices are classified into how many categories	57.5%	42.4%
The device "Bone Marrow needle" comes under which category	65.9%	34.1%
What is the full form of MvPI	59.5%	40.5%
What type of adverse events related to medical devices can be reported	88.5%	11.5%
In India which regulatory body is responsible for monitoring medical device associated adverse events (MDAEs)?	67.5%	32.5%

Table 2: Attitude of professionals towards Materiovigilance

	No. of Professionals (n=252)	%
Are you aware that medical device can cause an adverse event in a patient	251	99.6
Do you agree, it is the duty of doctor to report an adverse event related to medical device	239	94.8
Are you of the opinion that, reporting an adverse event due to medical device will improve patient safety	250	99.2
What is your opinion about establishing a Medical Device Adverse Event Monitoring Centre in your college	224	88.9
Do you think Materiovigilance should be taught in detail to health care professionals	242	96.0

Table 3: Attitude of professionals towards Materiovigilance according to designation

			Designation		
	Doctor (n=140)	Intern (n=41)	Nurses (n=49)	Pharmacist (n=6)	OT Technician (n=16)
Are you aware that medical device can cause an adverse event in a patient	140 (100%)	41 (100%)	48 (98%)	6(100%)	16(100%)
Do you agree, it is the duty of doctor to report an adverse event related to medical device	129 (92.1%)	41 (100%)	48 (98%)	6(100%)	15(93.8%)
Are you of the opinion that, reporting an adverse event due to medical device will improve patient safety	140 (100%)	41 (100%)	47 (95.9%)	6(100%)	16(100%)
What is your opinion about establishing a Medical Device Adverse Event Monitoring Centre in your college	133 (95%)	41 (100%)	29 (59.2%)	6(100%)	15(93.8%)
Do you think Materiovigilance should be taught in detail to health care professionals	133 (95%)	41 (100%)	47 (95.9%)	6(100%)	15(93.8%)

Table 4: Practice of professionals towards Materiovigilance

	No. of Professionals (n=252)	%
Have you ever encountered a medical device related adverse event during your practice?	71	28.2
Have you ever reported an adverse event related to a medical device?	26	10.3
Have you ever come across the MDAE reporting form?	42	16.7
Have you ever been trained on how to report medical device related adverse events?	50	19.8
Do you regularly monitor for adverse events in patients with medical devices?	132	52.4

DISCUSSION

Each year, FDA receives several hundred thousand reports of suspected deaths, serious injuries, and malfunctions involving medical devices. Early, routine reporting of adverse events, incidents, and near misses related to drugs and devices can ensure that performance and system issues are investigated, problems are corrected. Medical Device Reporting (MDR) is one of the post-market surveillance tools

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FDA uses to monitor device performance, identify potential safety issues, and contribute to the benefit-risk assessment of these devices. Because medical devices play a critical role in saving lives, many countries, including India, have established their own post-market surveillance system under the WHO directive. The Government of India has approved and launched the Materiovigilance Programme of India (MvPI) whose sole objective is to monitor the safety and quality of medical devices in the country.

Adequate knowledge of Materiovigilance is required to report adverse events related to medical devices. Our study will raise awareness of Materiovigilance among health care professionals so that they are sensitized and motivated to report adverse events related to medical devices that they encounter in their routine clinical practice and promote the safety, quality, and effective use of medical devices.

In our study, we found that most health care professionals who participated in this study were aware of adverse event reporting related to medical devices; only 50% of health professionals were familiar with the Materiovigilance programme of India. These findings agree with the studies done by Bikash Ranjan Meher et al,[3] and a positive attitude toward reporting adverse events related to medical devices was observed in a similar study by Modi et al.[6]

In another study in a tertiary teaching hospital in southern India, it was found that knowledge about the various aspects of Materiovigilance was adequate and attitudes toward reporting MDAE were positive (9). Many of the participants in our study had not participated in any medical device related adverse event reporting training programme and about 96% of them felt that a Materiovigilance training programme should be implemented for healthcare professionals.

More than half of the participants regularly comply with the MDAE, but most of them had not seen the MDAE form and they did not know how to report adverse events related to medical devices. Nonreporting or underreporting of MDAE is widespread. Materiovigilance is a relatively new and few hospitals in India have been included in the MvPI. Lack of knowledge about the importance of Materiovigilance is a major problem. In a study, healthcare professionals cited several factors, such as the lack of an adequate reporting system and the lack of an enabling environment, as some of the barriers to the use of Materiovigilance.[5-10]

As healthcare professionals, we have an obligation to ensure that our patients receive the optimal care and safety when using medical devices. It is important, therefore, that we stay informed about the importance of reporting medical device-associated adverse events (MDAEs). To ensure that these reports are reported effectively, it is essential to raise awareness among healthcare professionals about the importance of reporting MDAEs, and make sure those professionals receive regular training on how to report MDAEs. Moreover, active monitoring by an institutional expert committee on Materiovigilance can help optimize reporting practices and contribute to a successful implementation of a Materiovigilance programme

The limitation of this study is its single-centre focus.

CONCLUSION

The importance of Materiovigilance (Mv) in improving patient safety has been widely recognized. This study aimed to evaluate the awareness and practice of Materiovigilance among healthcare professionals and assess the potential for improving it through increased awareness and stronger enforcement of existing Materiovigilance activities. The results suggest that creating awareness and strengthening existing Materiovigilance activities are key strategies for successfully implementing the Materiovigilance Patient Intervention (MvPI) programme.

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