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KNOWLEDGE, ATTITUDE, AND PRACTICE OF MATERIOVIGILANCE AMONG HEALTHCARE PROFESSIONALS IN A TERTIARY CARE TEACHING HOSPITAL: A CROSS SECTION SURVEY

Pharma

Dr Shruti Chandra* MBBS, MD Associate Professor, Department Of Pharmacology, MGM Medical College And Research Centre, Maharashtra, India *Corresponding Author

Mr Rahil Sheikh Msc CR, Clinical Research Coordinator, Department Of Pharmacology, MGM Medical College And Research Centre, Maharashtra, India

Dr Deepak Bhosle MBBS, MD Professor, Department Of Pharmacology, MGM Medical College And Research Centre, Maharashtra, India

ABSTRACT

Background: Materiovigilance involves monitoring and ensuring the safety of medical devices. There is a gap in understanding and awareness among healthcare professionals regarding Materiovigilance protocols and practices. The study aims to assess healthcare professionals' knowledge, attitudes, and practices towards Materiovigilance. **Methods:** Convenience sampling was used to select 280 participants, including doctors, nurses, and technicians. Data questionnaires was filled through interview. The questionnaire had two parts, first included demographic profile and second contains knowledge, attitude and practice questions. Data was entered in Microsoft Excel and analyzed using SPSS version 25.0. **Results:** The study revealed moderate knowledge among participants, awareness of Materiovigilance programs and understanding of low-risk medical devices. Specifically, 67% of participants were aware of the Materiovigilance Program of India (MVPI), while 73% could identify low-risk medical devices. Attitudes towards Materiovigilance were generally positive, with 91% of participants believing in the link between adverse events and medical devices, and 83% acknowledging the importance of reporting such events for patient safety. Despite high awareness of reporting centers (78%) and workshops, actual reporting rates (13%) and attendance (32%) were relatively low. **Conclusion:** This survey examines healthcare professionals' understanding, views, and actions regarding Materiovigilance in a teaching hospital. It seeks to assess awareness and compliance with India's Materiovigilance program, aiming to identify ways to improve patient safety. While some strengths were identified, such as adequate knowledge and positive attitudes, there is a need for improved implementation through increased reporting and education.

KEYWORDS

Materiovigilance, Healthcare professionals, Knowledge, Attitude, Practice

INTRODUCTION

The system of monitoring and ensuring the safety of medical devices is known as Materiovigilance. Any "apparatus, appliance, software, and material, whether used alone or in combination, together with other medical devices" is classified as a medical device by the World Health Organization (WHO).[1] The WHO has suggested essential diagnostics list like the essential medicines list in recognition of the growing significance of medical devices in the administration of health care.[2] The tools, software, and combinations that medical professionals employ to identify, treat, prevent, and manage diseases are known as medical devices. In addition to analyzing and controlling body processes, they help in the management of injuries, diseases, and disabilities. Prominent medical achievements, from diagnosis to breakthrough discoveries, are the aim of the manufacturers that produce these devices.[3] They play a significant role in the identification, management, and prevention of several illnesses. Simple devices like tongue depressors and thermometers, to intricate life-saving devices like heart valves and stents, are among them.[4]

Materiovigilance deals with post-market surveillance of medical devices, including in-vitro diagnostics, while pharmacovigilance focuses on post-market surveillance of medicinal products.[1] Adverse event is any unintended medical occurrence, unintended disease or injury, or inconvenient clinical signs in subject users or persons, whether related to the medical devices or related to medicinal products. [5] Medical device malfunctions are a common cause of accidents. Some really undesirables happen when medical devices don't work properly. Like babies getting hurt because incubator fires, or people getting sick from hip implants. So, the Government of India's Ministry of Health and Family Welfare said okay to the Materiovigilance Programme of India. To deal with all the Adverse event that happens because of medical devices.[6]

Due to the rising prevalence of stroke, obesity, diabetes, cancer, and many other chronic conditions, the global market for medical devices increased dramatically, from 260 billion USD in 2006 to 380 billion USD in 2016.[7] India has a medical equipment market worth USD 3.1 billion. [8] The Ministry of Health and Family Welfare (MoHFW), Government of India, has authorized the Materiovigilance Program to handle potential adverse occurrences related to medical devices. "The Materiovigilance Program of India (MvPI) was initiated on July 6, 2015, in India to educate healthcare professionals on the significance of reporting medical device-associated adverse events (MDAEs) and producing independent, reliable, evidence-based safety data for medical devices.[9] Furthermore, the Indian government has issued the Medical Devices Rules 2017 to govern the safe use of medical devices in the country. Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) functions as the National Collaborating Centre for the Materiovigilance Programme of India.[10] The basic goal of this program is to create awareness of adverse event and collect independent reliable evidence-based safety data of medical device and to share it among health providers across the nation. Medical gadgets benefit patients, yet there are still certain risks associated with using them. It may result in the morbidity and mortality of medical device users.[11]

Therefore, this study aimed to assess the awareness of healthcare professionals' knowledge, attitude, and practice regarding Materiovigilance in a tertiary care teaching hospital.

MATERIAL AND METHODS

This study employed a cross-sectional survey design to assess the knowledge, attitude, and practice of Materiovigilance (Mv) among healthcare professionals in a tertiary care teaching hospital. The study included healthcare professionals working at a Tertiary Care Teaching Hospital, including doctors, nurses, and technicians. Participants were selected using convenience sampling, with efforts made to ensure representation from different departments and levels of experience. The survey had two parts: the first gathered socio-demographic data, including age, sex, and work experience. The second part consisted of 15 questionnaires assessing Materiovigilance understanding (questions 1-5), MDAE reporting perspective (questions 6-10), and Materiovigilance implementation (questions 11-15). The "knowledge" section had five questions, with scores ranging from 0 to 5. Participants were classified based on their knowledge score compared to the median. The "attitude and practice" section had binary questions with scores up to 10, contributing to a KAP total score. In response to question 15, participants identified factors influencing their MDAE reporting.

Statistical Analysis

Data wase entered in Microsoft Excel and analyzed using SPSS version 25.0 Mean and SD will be calculated for quantitative variables and proportions will be calculated for categorical variables. Also, data will be represented in form of visual impression like bar diagram etc.

OBSERVATIONS AND RESULTS

Demographic Characteristics

The survey form was distributed to 280 medical professionals working at medical centers, and all 280 responded in full. The ordinary response rate across all participants was 72.13%.

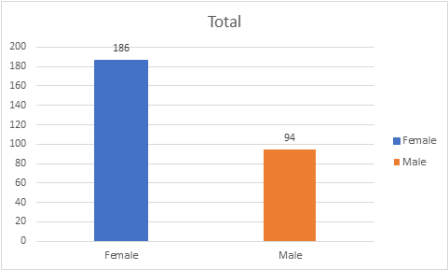

Fig 1: Bar-diagram Distribution of data on the basis of Gender

The data distribution according to graph No 1, to analysis revealed that the maximum number of female health care professionals' participants were male, i.e., 94, with 33.57 % Whereas, the number of female participants was 186, with 66.43%, making the ratio balanced.

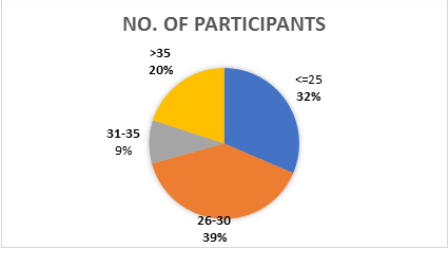

Fig No 2. Distribution of data on the basis of Age

The pie diagram shows, the data distribution of age groups of the subjects among which the range of the age group of 26 to30 hights i.e. 39.29% (110 participants) in the age >35 years of age were 56 participants come to be 20%, in the age 31-35year of age were 26 participants comes to be 9.29%, in the age <=25 year of 88 participants comes to be 31.43% the minimum range of percentage of health care professionals. Mean age participants in the study were 30.02 years with standard deviation 7.74.

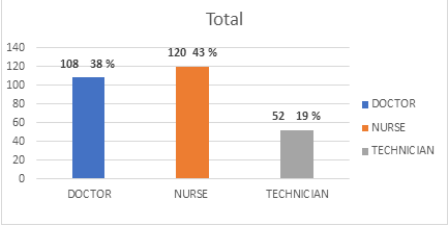

Fig No 3: Bar diagram Distribution of data on the basis of Occupation

The bar diagram (Figure 3) illustrate the distribution of data concerning the occupation groups of the participants. Among them, 108 were doctors, 120 were nurses, and 52 were technicians, representing the smallest group of participants in this study. Notably, nurses exhibited the highest number of participants in the study, totalling 120 individuals, representing an average percentage of 43%. Furthermore, the study included 108 doctors, constituting an average percentage of 38.%. Additionally, a minimum of 52 technician participants took part, with an average attendance rate of 19%.

Table No 1: Knowledge About MV Among Health Care Professionals As Percentage Of Correct Responses

Question no.	Question	"Yes" response by Total N = 280 N /%
1	Which of the following is the Medical Device?	188 (67%)
2	What is the materiovigilance ongoing program in India for monitoring adverse events due to medical device?	188(67%)
3	What is the full form of MDMC?	120(43%)
4	Example of low-risk medical device?	203(73%)
5	How many basic classifying devices are there in India?	191(68%)

The table show that healthcare professionals have varying knowledge about medical devices, with 67% correctly identifying them and 67% knowing about India's adverse event monitoring program. However, only 43% know the full MDMC form, 73% can identify low-risk devices, and 68% correctly identify basic classifying devices.

Table No 2: Attitude Base Question About MV Among Health Care Professionals As Percentage Of Correct Responses

Question no.	Question	"Yes" response by Total N = 280 N /%
6	Do you believe that a patient's adverse Event occurrences could be caused by medical devices	254(91%)
7	Do you agree that doctors have a duty to disclose adverse medical device events	169(60%)
8	Do you believe that disclosing bad events will improve patient safety?	231(83%)
9	If so, do you believe it is essential to report any negative side effects related to the medical device?	241(86%)
10	Do you know adverse event can be reported throughout MVPI?	186(66%)

The table shows healthcare professionals' beliefs and practices regarding adverse events caused by medical devices. 91% believe medical devices can cause adverse events, 60% agree that disclosing such events and reporting negative side effects is essential for patient safety, and 83% believe disclosing adverse events would enhance safety, were it is essential to report any negative side effects related to the medical device 86%, though 66% are adverse event can be reported throughout MVPI.

Table No 3: Practice Base Question About MV Among Health Care Professionals As Percentage Of Correct Responses

Question no.	Question	"Yes" response by Total N /%
Q11	Do you know Department of Pharmacology is centre for reporting of Medical Device Adverse Event in MGM Medical College & Hospital?	219(78%)
Q12	Have you ever reported any MDAE?	36(13%)
Q13	Have you seen the medical device adverse event reporting form prepared by CDSCO?	74(26%)
Q14	Have you ever attended any workshop or CME focused on safety of medical device?	89(32%)
Q15	Have you ever experienced MDAE occurring in a patient during your professional practice ?	69(25%)

The table shows that 78% of healthcare professionals at MGM Medical College & Hospital acknowledge the Department of Pharmacology as the center for reporting MDAEs, but only 13% have personally reported any. Additionally, 26% have seen the CDSCO-prepared form, 32% have participated in safety workshops, and 25% have encountered MDAEs in their professional practice.

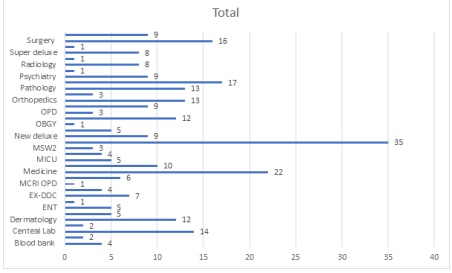

Fig No 4: Distribution of Medical Vigilance Responses Across Hospital Departments"

When comparing departments across different categories, "Nephrology" has the most number with 35, closely followed by "Medicine" with 22 departments. "Psychiatry," "Orthopedics," and

"Pediatrics" are examples of moderately sized departments with counts between 9 and 17. On the other hand, a number of departments, including as "Casualty," "Dental," "ENT," and "MCRI OPD," have lower numbers, which range from 1 to 7. Remarkably, only one department represents some departments, such as "Superintendent Office," "OBGY," "Psychology," and "Respiratory Medicine." This graph provides a visual representation of the departments' distribution among several categories.

DISCUSSION

It is defined as a well-coordinated system for identifying, compiling, documenting, and analysing any adverse occurrences related to the use of medical devices, as well as for protecting the patient's health by preventing a recurrence.[12] An active, well-organized surveillance system is crucial for promoting safe and high-quality use of medical devices, which can enhance patient safety and the healthcare system.[13] MvPI's main objective is to educate stakeholders about the importance of MDAE reporting.[14] There are a number of KAP studies on pharmacovigilance among medical professionals; however comparatively few KAP surveys are carried out about materiovigilance. One such initiative to raise awareness and examine the case's current state is the current study.

According to the complexity, purpose, and invasiveness of the MDs, the effects of MDAEs differ.[15] Simple, non-invasive medical devices often cause minor side effects, while invasive and sophisticated devices can lead to serious adverse events, life-threatening risks, hospitalization, disability, or death.[13] The use of post-marketing surveillance (PMS) ensures the safety of medical devices that are licensed.[16] Although post-marketing surveillance is primarily the responsibility of producers, regulatory agencies play a specific role at different stages.[17]

The study showed that many healthcare professionals were familiar with India's materiovigilance program, which tracks adverse events from medical devices. Out of 280 participants, 67% knew about the ongoing MvPI program, 67% were aware of its full form, and 41% knew about the involvement of the Medical Device Monitoring Centre. Additionally, 73% were aware of low-risk medical devices, and 68% understood how devices are classified in India.

The study from the India Institute of Medical Sciences in Bhubaneswar, Odisha, conducted by Meher BR, Padhy BM, et al., highlighted that a small percentage of participants (26.7% faculty and 41.7% overall) were aware of the Indian Government's program for monitoring MDAE ($P = 0.11$), indicating a knowledge gap among medical professionals regarding adverse event reporting and the materiovigilance program. The mean knowledge score for materiovigilance was low at 2.09 ± 1.06, compared to pharmacovigilance. In contrast, our study demonstrated a moderate knowledge score of 5.66 ± 1.43.[2]

According to Alsohime F et al.'s questionnaire survey of 297 ICU nurses in Saudi Arabia, the participants' knowledge of MDAEs was lacking.[18]

In our study, an attitude-based questionnaire involving 280 healthcare professionals revealed that 91% believe adverse events from medical devices can cause a patient's health issues. However, only 77% of doctors agree on the duty to disclose such events, while 48% of technicians and 52% of nurses disagree. Despite this discrepancy, 83% believe that disclosing adverse events improves patient safety, and 86% consider reporting negative side effects essential. Furthermore, 66% are aware of the option to report adverse events through MVPI."According to our attitude-based questioner study involving 280 healthcare

A Coyle et al. study found that postgraduate medical students' reporting attitudes were positively affected by early exposure to the medical education program on medical device-induced adverse event reporting. Health workers' reporting culture can be improved and awareness raised by institutions' training programs.[19]

The majority of medical professionals (78%) are aware that MGM Medical College & Hospital's Department of Pharmacology is the main center for reporting Medical Device Adverse Events (MDAEs). Only 13% of respondents, However, have really reported any MDAEs. Furthermore, although many people (26%) are aware of the MDAE reporting center, only 32% have participated in medical device safety-focused seminars or continuing medical education (CMEs). Finally, 25% of respondents said that they personally experienced MDAEs in patients when working in their field.

According to research by Gagliardi et al., medical experts listed a number of obstacles to the practice of materiovigilance, including inadequate reporting systems and unfavourable environments.[20] Therefore, we identified that, based on age or position, the reporting culture among medical professionals might improve if initiatives such as workshops, continuous medical education, and other training programs raise their awareness.

The study's limitations include the fact that it was limited to one institute and one small community, making it cannot to accurately reflect the understanding and approaches of healthcare professionals across India.

SUMMARY AND CONCLUSION

The medical devices and healthcare industry has experienced significant growth in recent years, playing a crucial role in diagnosing illnesses, overseeing treatments, aiding disabled individuals, and treating both short and long-term conditions.

This cross-sectional survey investigates the knowledge, attitude, and practice of materiovigilance among healthcare professionals in a tertiary care teaching hospital. The study aims to assess the level of awareness and adherence to materiovigilance program of india, shedding light on potential areas for improvement in patient safety. While there are areas of strength, such as adequate knowledge levels and positive attitudes towards Materiovigilance, there are also areas for improvement, particularly in translating knowledge into practice through increased reporting rates and participation in educational initiatives.

There is a need to conduct various educational and training programs to improve the practice of reporting and thereby contributing to the safety of MD usage.

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