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A Study on Knowledge, Attitude and Practice of Materio-Vigilance among Allied Health Students at A Tertiary Care Institute – A Cross Sectional Study

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Abstract

Background: Medical devices are necessary in the diagnosis, monitoring, and management of various diseases. Materiovigilance is the process to study and follow incidents that might result from using medical devices. Many allied health students are not aware of the current Materiovigilance Programme of India initiated by the Government of India to monitor medical device adverse events which is necessary to analyze benefit risk ratio and generate evidence based information on safety of medical devices (deficient pacemaker may risk the life of the patient).

Aim and Objective: The aim of the study is to assess the knowledge, attitude and practice of Materiovigilance among allied health students in a tertiary care hospital.

Material and Methods: It is a cross sectional study conducted among allied health students in a tertiary care institute, participants were selected through random sampling. A self-structured questionnaire was used containing 15 pre-validated questions with 5 questions on Knowledge, 4 based on Attitude and 6 based on Practice and their responses were recorded. Data's collected were entered in Microsoft Excel and analyzed using SPSS version 23.0.

Results: Among the 125 study participants majority around 62.4% were females and rest were males. The mean age of participants was 20.1 ± 2.3 years ranging from 19 – 21 years. Among them 70 % had optimal knowledge on materiovigilance, 90% had positive attitude on MDAE and its reporting while only 32 % have implemented in their routine work .

Conclusion: The study participants lacked the necessary transitional knowledge and positive attitude to good practice of MDAE reporting. Therefore, it is essential to organize regular workshops and training sessions for students to improve their spontaneous reporting of MDAEs, taking into account these deficiencies and the many factors influencing MDAE reporting.

KEYWORDS: *Medical devices, Medical device-associated adverse events (MDAEs), Materiovigilance.*

INTRODUCTION

Medical devices (MDs) greatly impact medical practice, and the innovation and variety within this business enhance the efficacy and quality of treatment. Medical devices have a crucial role in diagnosis, prevention, treatment, and management of illnesses, encompassing a broad spectrum of products, from basic bandages to life-saving technologies such as stents. The widespread utilization of medical devices in healthcare has resulted in a concerning increase in medical device-associated adverse events (MDAEs).[1,2]

In July 2015, the Indian Pharmacopoeia Commission (IPC) served as the national coordinating center for the Materiovigilance Program of India (MvPI), which was introduced under the regulation of the Indian Health Ministry. The Indian government released the Medical Devices Rules 2017 to regulate the safe utilization of medical devices in the country. The safety of medical devices and their regulation have been under scrutiny in

recent years because of the numerous accidents linked to medical devices that have been reported in various nations. In India, around 1931 reports of MDAEs were received by IPC from July 2015 to October 2019. [3,4]

The spontaneous reporting of Medical Device Adverse Events (MDAEs) by healthcare workers (HCWs) and other stakeholders is essential for the effective operation of the medical device monitoring system. Healthcare workers are essential in materiovigilance by reporting adverse occurrences associated with medical devices. Research indicates that healthcare workers are largely ignorant about materiovigilance and under-reporting is mainly because of ignorance, insufficient training, and a sense of administrative burden. [5,6,7] Hence effective adverse event reporting relies heavily on the knowledge, attitude, and practice (KAP) of these professionals which is necessary to analyze benefit risk ratio and generate evidence based information on safety of medical devices

AIMANDOBJECTIVE:

- The aim of the study is to assess the knowledge, attitude and practice of Materiovigilance among allied health students in a tertiary care hospital.

METHODOLOGY

- Study design
  A cross-sectional study
- Study area
  Department of Pharmacology, Melmaruvathur Adhiparasakthi Institute of Medical Sciences and Research (MAPIMS)
- Study duration
  3 months(Jan 2024-Mar 2024)
- Study population
  Allied Health students (Final year)
- Inclusion criteria
  Allied Health students (Final year) of both sexes.
- Exclusion criteria
  Participants not willing to give consent
- Sampling technique
  Convenient sampling
- Sample size: 125
- Data collection

Data was collected in Department of Pharmacology in MAPIMS, Melmaruvathur. A total of 125allied health students were enrolled for this study.The study was done by the principal investigator. After getting IEC approval and informed written consent from the participants, a competency- based questionnaire was used to assess the knowledge, attitude and practice among the study participants. The questionnaire consists of 4 parts which are as follows:

- Part 1- demographic details
- Part 2 - 5 questions to assess the knowledge about materiovigilance
- Part 3 – 4 questions to assess the attitude towards materiovigilance
- Part 4 – 6 questions to assess the practice of materiovigilance

- Data Analysis:

Data was entered in Microsoft excel 2019 and analysed using software SPSS (Statistical Package of Social Sciences) version 23. Continuous variables and categorical variables were interpreted using frequencies (mean±SD) and proportions (%).

- Ethical issues

- The study was approved by the Institutional Ethical Committee, (IEC) MAPIMS.
- Participants were informed about the study and informed that data's are kept confidential

RESULTS

The present cross-sectional study was conducted at Department of Pharmacology, MAPIMS for a period of three months. A total of 125 study participants were enrolled for this study. The results of the study are as follows

Demographic details

Out of 125, 62.4% were females and the mean age of participants was 20.1 ± 1.3 years ranging from 19 – 21 years.

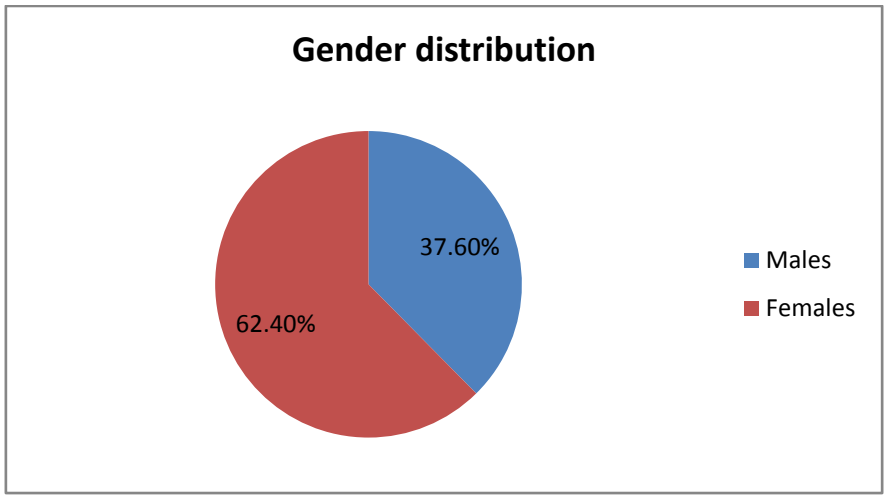

Figure 1: Gender Distribution

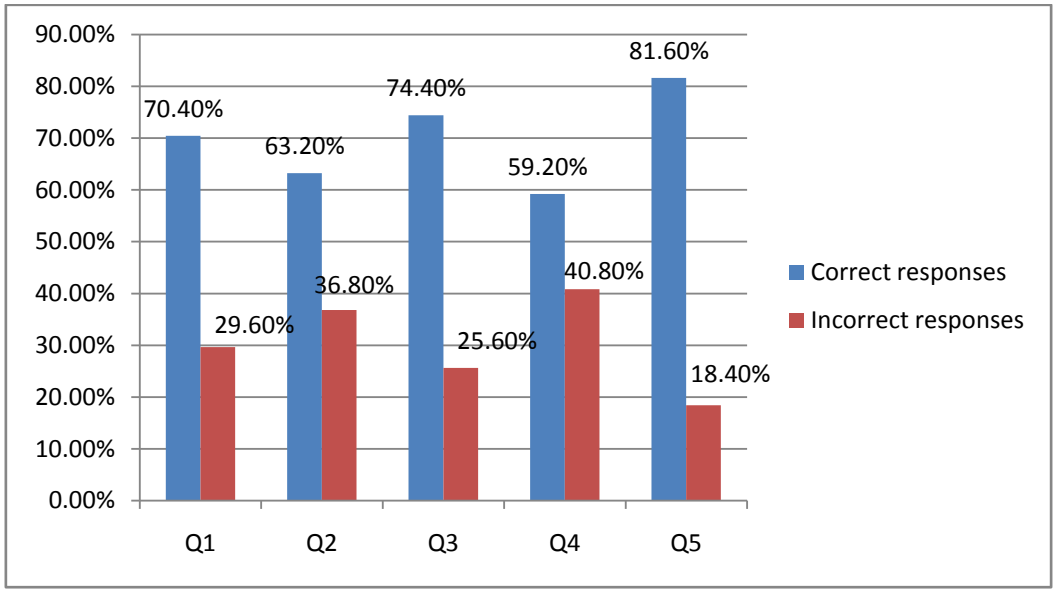

Figure 2: Knowledge about materiovigilance among study participants (n=125)

Figure 2 depicts that there were a total of five questions in the questionnaire to assess the knowledge of study participants regarding materiovigilance. Among 125 study participants, 79 (63.2%) participants gave correct responses regarding the basis of classification of medical devices into various categories, and 93 (74.4%) participants were aware regardingcategory of devices. The awareness among participants about medical

device-induced adverse events was found to be 81.6 %. The overall knowledge about materio-vigilance was found to be 69.7%

Table 1: Attitude towards materiovigilance

Questions	Yes	No
1. Do you think medical devices can cause adverse events in the patient?	105(84%)	20(16%)
2. If yes, do you think reporting of any adverse events associated with the medical device is necessary?	93 (89%)	12 (11%)
3. Do you agree it is the obligation of doctors to report adverse events due to medical device?	115(92%)	10(8%)
4. Do you think reporting of adverse event will enhance patient safety?	118(95%)	7(5%)

Table 1statesattitude towards materiovigilance and it was found that majority 84% of participants agreed that medical devices can cause an adverse event while 92 % of participants believed, it is a medical professional's responsibility to report every medical device induced adverse event, 95% of study participants agreed that reporting medical device-induced adverse events can improve patient safety. The study also found that study participants had positive attitude on MDAE and its reporting.

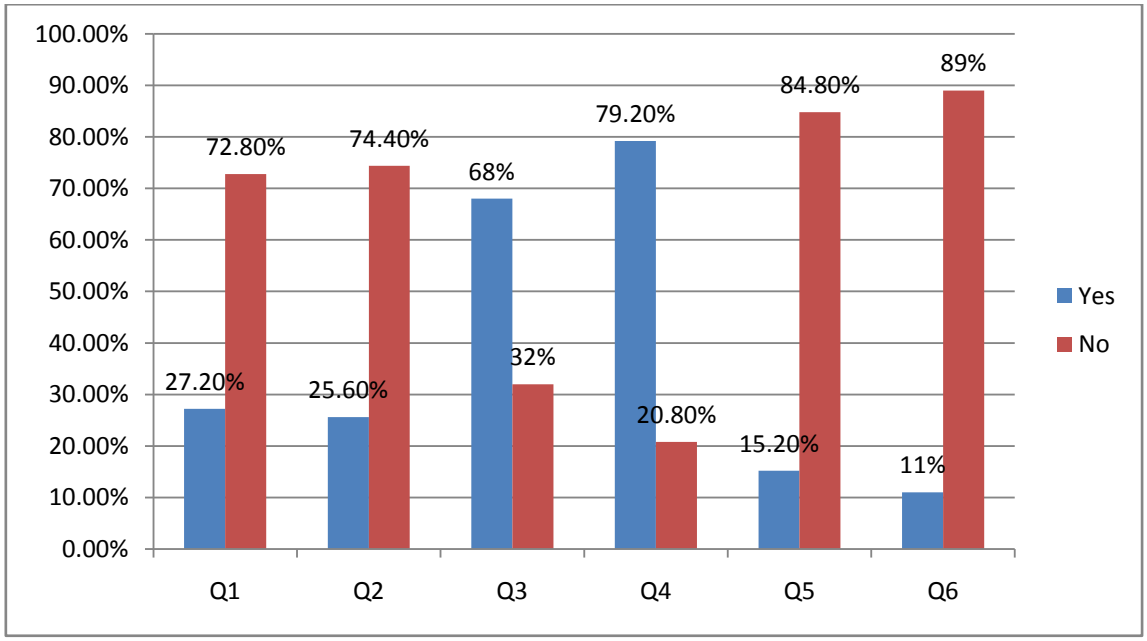

Figure 3: Practice of materiovigilance among study participants

Figure 3 explains about regarding practice of materiovigilance and found that only 27.2% had experienced the adverse events during the usage of medical device. Unfortunately only 15.2% of the participants had seen medical device adverse event reporting form and only 11% of the participants had attended awareness sessions (CME/ Workshop) focused on safety of medical device.

DISCUSSION

The present observational study found that among the 125 study participants majority around 62.4% were females and rest were males. The mean age of participants was 20.1 ± 2.3 years ranging from 19 – 21 years.

Among the 125 study participants around 70 % had optimal knowledge on materiovigilance. A study by Sojitra et al.[8] found that approximately 77% of participants had acquired direct or indirect knowledge on materiovigilance which is compared to our study report. Another study by SivagourounadinK[9] also stated that around 68% of healthcare workers had adequate knowledge which is also similar to our study report. Another study by Selvam et al[10] also found that only 40% had adequate knowledge in materiovigilance which is in contrast to our study report. The comprehensive knowledge in health care workers is essential for thorough adverse event documentation.

Our study stated that majority around 90% had positive attitude on MDAE and its reporting. Raju et al[11] conducted a study and found that a significant majority of respondents (80.85%) agreed that reporting Medical Device Adverse Events (MDAEs) represents a professional responsibility, acknowledging its potential advantages for patient care. These respondents showed a strong positive attitude regarding MDAE reporting which is similar to our study report. A similar positive attitude toward reporting adverse occurrences linked to medical devices was found in a study by Kurien et al which is also comparable to our study report.[12]

Only 32% of students have included MDAE reporting into their regular work, despite the fact that the majority of them had a favorable opinion toward it. Our study is similar to a study by Sojitra et al., which found that only 26% of respondents had reported the MDAE. This disparity indicates a major area that needs improvement. Numerous studies have shown that there are obstacles to reporting, such as a lack of time, ignorance, or fear of legal repercussions, which must be addressed with focused interventions. Additionally, Raju et al. said that their study's adverse event reporting procedures were poor. Many of them did not take part in any training sessions pertaining to reporting adverse events, nor did they report any adverse events. This may be the outcome of insufficient awareness and reporting protocols.

Nirmalya Manna et al.[13] evaluated staff nurses' knowledge, attitudes, and practices of medico-vigilance in a medical college setting. The study found that when it came to reporting Medical Device Adverse Events (MDAEs), there was a lack of effective implementation of supporting information and a supportive attitude. The study concluded that implementing a variety of training initiatives, including workshops and Continuing Medical Education (CME) sessions, could help staff nurses improve their MDAE reporting habits.

The Materiovigilance knowledge, attitude, and practice of medical surgeons in Gujarat were evaluated by Panchal YN et al.[14] Only a small percentage of the 156 participants knew about India's present program for tracking adverse events that occur during medical practice. However, the majority of participants said that they would be willing to report adverse events related to medical devices (MDAEs). The study's findings emphasized the necessity of a range of training initiatives and educational activities to support and encourage the reporting of adverse events caused by medical devices.

CONCLUSION

Among the participants of this study the attitude towards materiovigilanc and its importance wasoptimal. Yet knowledge on the current programmes and reporting protocols were deficient which led toinadequate implementation of reporting in their practice. Adequate training and continuous medical education are needed to improve the current standards of knowledge and practice of materiovigilance.

CONFLICT OF INTEREST: NIL
FUNDING: NIL

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QUESTIONNAIRE

KNOWLEDGE

1) What is India's current program for monitoring adverse events caused by medical devices?
   a) Medical devices safety program of India
   b) Medical devices single audit program of India
   c) Materiovigilance program of India
   d) Pharmacovigilance program of India
2) On which basis medical devices are classified into various categories (A, B, C, and D) in India?
   a) Based on the risk they carry while their use
   b) Based on their price
   c) Based on the condition (s)/disease (s) for which they are being used
   d) Based on their complexity of structure
3) Which of the following medical device belongs to category D?
   a) Ventilator
   b) Bandage
   c) Pacemaker

d) Orthopedic implant

4) What is the time period to report serious medical device adverse event?
   a) within 10 calendar days
   b) within 15 calendar days
   c) within 20 calendar days
   d) within 30 calendar days
5) What is a reporting system available in India to report MDAEs (Medical device-induced adverse events)?
   a) By toll-free helpline number - 1800 180 3024
   b) By Medical Device Adverse Event (MDAE) reporting form
   c) By MDAE Reporting Mobile Application
   d) All of the above

ATTITUDE

1. Do you think medical devices can cause adverse events in the patient?YES/NO
2. If yes, do you think reporting of any adverse events associated with the medical device is necessary?YES/NO
3. Do you agree it is the obligation of paramedicsstaff to report adverse events due to medical device?YES/NO
4. Do you think reporting of adverse event will enhance patient safety?YES/NO

PRACTICE

1. Have you observed any adverse events due to medical device during your training period?
YES/NO2 .If yes, have you reported that?
YES/No
3.Have you seen monitoring of patients being done for any adverse outcome of implanted device beyond the recovery period?
YES/NO4. Have you observed any feedback for any untoward events from patients after implanting the device? YES/NO5. Have you seen the medical device adverse event reporting form prepared by CDSCO?YES/NO6. Have you ever attended any workshop or CME focused on safety of medical device?YES/NO