

KNOWLEDGE, ATTITUDE AND PRACTICE OF MATERIOVIGILANCE AMONG MEDICAL POSTGRADUATE STUDENTS

ADITI BHANDARI 

Department of Pharmacology, Ravindra Nath Tagore Medical College, Udaipur-313001, Rajasthan, India

*Corresponding author: Aditi Bhandari; *Email: draditibhandari@gmail.com

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ABSTRACT

Objective: Medical devices have become an indispensable part of the healthcare system in recent times. A major shift towards increasing demand and supply of devices has led to an increase in the number of adverse effects being reported from across the world. "Materiovigilance" (MV) is the coordinated system of identification, collection, reporting, and analysis of any untoward occurrences associated with the use of medical devices and protection of a patient's health by preventing its recurrences. Post-Graduate medical students play a key role in reporting and management of any adverse events associated with medical devices in patients. Therefore, this study was conducted to assess the knowledge, attitude and practice regarding Materiovigilance among the residents.

Methods: A cross-sectional observational study was conducted among the Post graduate students of a tertiary care government institute of Southern Rajasthan. A pre-validated questionnaire comprising of 18 questions pertaining to knowledge, attitude, and practice of Materiovigilance was used.

Results: Out of 110 participants ongoing programme 73.6% knew about an ongoing programme on Materiovigilance, 29.6% have been trained about MV while 70% consider reporting its ADR necessary, while 6.6% have reported ADRs caused by devices in their department.

Conclusion: A large section of PG students was aware of the term "Materiovigilance," but they need to be provided with more knowledge about the concept and its reporting. The attitude is positive but regular practice of reporting needs to be developed. Educational interventional programmes are required to promote Materiovigilance and ADR reporting due to medical devices in day-to-day practice.

Keywords: Adverse events, Adverse reactions, Materiovigilance program of India, Medical devices

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INTRODUCTION

With the rise in the incidences of adverse reactions due to innumerable drugs globally, National pharmacovigilance programmes were started in many countries. India also started its own Pharmacovigilance Programme of India (PvPI) in July 2010.

However, there was no provision for the adverse effects caused by the medical devices in daily use. Therefore, the Ministry of Health and Family Welfare launched the Materiovigilance Program of India (MvPI) in July 2015. The National Coordinating Centre of this programme is located at Indian Pharmacopoeia Commission (IPC), Ghaziabad, Uttar Pradesh and National Collaboration Centre is located at Shree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Chennai. In addition to this, Medical Devices Rules 2017 was issued by the Indian government to regulate the safe use of medical devices within the country [1].

Hence, we define "Materiovigilance" as the coordinated system of identification, collection, reporting, and analysis of any untoward occurrences associated with the use of medical devices and protection of patient's health by preventing its recurrences [2].

A device must be "substantially equivalent" to an existing marketed device, as demonstrated by product-specific performance requirements or "special controls." [3]

A vast variety of devices play a major role in today's practice of modern medicine. There are a number of stakeholders involved in the cycle of reporting of Medical Device Adverse Events (MDAE) which includes healthcare professionals (HCPs), Pharmacists, biomedical and clinical engineers, pharmacists, nurses and laboratory technicians.

Among the intense training schedule throughout the period of residency, post-graduate medical students are the first point of contact between patients and such devices. Thus, these residents are a key aspect in reporting adverse events associated with medical devices that occur in day-to-day practice. Lack of knowledge, ignorant attitude, and poor practice of Medical Device Adverse Event (MDAE) reporting was observed among HCPs in studies carried out in other countries.

However, at present, there are very few published studies pertaining to their knowledge, attitude, and practice about materiovigilance in our country. Therefore, this study was planned to identify the awareness and perspective regarding Materiovigilance among the residents and to create enlighten them about the difference that the Postgraduate students of a tertiary care government institute of Southern Rajasthan can make by small efforts from their end in its practice.

MATERIALS AND METHODS

Study design-A cross-sectional questionnaire-based observational study

Study duration-3 mo

Study population-110 Postgraduate students of a tertiary care government institute of Southern Rajasthan

Inclusion criteria-All PG students who responded

Exclusion criteria-

- Those not willing to be a part of the study
- Nursing officers
- Pharmacists

Study tool

A questionnaire comprising of 18 questions pertaining to knowledge, attitude, and practice of materiovigilance and ADR reporting, developed using Google forms.

Data collection

A structured questionnaire was developed in English language based on previous studies conducted in the field of medical devices vigilance in other countries. The contents of the questionnaire were reviewed and validated by senior experienced faculty of the Department of Pharmacology in a tertiary care teaching hospital. After explaining the purpose of the study in detail, written informed consent was obtained and the questionnaire was shared with post-graduate medical residents. The results were procured anonymously.

The questionnaire comprised of three sections.

1. Informed consent
2. Questions to evaluate knowledge,
3. To assess the attitude of the Post Graduate residents,
4. To note practice towards Materiovigilance and ADR reporting.

Data analysis

The data was entered in MS Excel and analysed using descriptive statistics.

Ethical clearance was obtained from the Institutional Ethics Committee.

The entire study was planned and conducted in accordance with the principles of Good Clinical Practice, the ethical standards of the responsible committee on human experimentation, the Helsinki Declaration of 1975, and Indian Council of Medical Research-National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017). The manuscript was prepared in accordance with "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" developed by the International Committee of Medical Journal Editors (October 2008).

RESULTS

In this study, out of 130 postgraduates, 110 students responded, indicating a response rate of 84.6%. The average value of the correct response for knowledge, attitude and practice towards Materiovigilance and ADR reporting were calculated to be 37.6%, 72.7% and 20.86% respectively (table 1-3).

Table 1: Knowledge-based questions

S. No.	Question	Response			
		Correct		Incorrect	
		%	No.	%	No.
1	Do you know about any ongoing programme related to material and its safety in India?	73.6%	81	26.3%	29
2	What is the ongoing programme in India for monitoring adverse events due to medical devices?	48.2%	53	51.8%	57
3	Which of the following devices can be reported?	34.5%	38	65.5%	72
4	Who can report an adverse event due to medical device?	37.3%	41	62.7%	69
5	How can ADR due to any material be reported?	40.9%	45	59.1%	65
6	Which of the following belong to the wrong category?	42.7%	47	57.2%	63
7	Where is the National Coordination Centre for MvPI located?	19.1%	21	80.9%	89
8	Which of the following is not included in basis of classifying medical device?	4.5%	5	95.4%	105
	Mean:	37.6%		62.4%	

Table 2: Attitude based questions

S. No.	Question	Response			
		Correct		Incorrect	
		%	No.	%	No.
1	Do you think medical devices can cause adverse events in the patient?	83.6%	92	16.3%	18
2	If yes, do you think reporting of any adverse events associated with the medical device is necessary?	70.0%	77	30.0%	33
3	Do you agree it is the obligation of doctors to report adverse events due to medical device?	71.9%	79	28.1%	31
4	Do you think reporting of adverse event will enhance patient safety?	65.4%	72	34.5%	38
	Mean:	72.7%		27.2%	

Table 3: Practice-based questions

S. No.	Question	Response			
		Correct		Incorrect	
		%	No.	%	No.
1	Have you ever encountered any adverse events due to medical device during your practice?	13.2%	15	86.8%	95
2	If yes, have you reported that?	6.6%	7	93.4%	103
3	Do you monitor the patients for any adverse outcome of implanted device beyond the recovery period?	38.6%	35	51.4%	65
4	Do you take any feedback for any untoward events from patients after implanting the device?	25.4%	28	74.6%	82
5	Have you seen the medical device adverse event reporting form prepared by CDSCO?	11.8%	13	88.2%	97
6	Have you ever attended any workshop or CME focused on safety of medical device?	29.6%	27	70.4%	83
	Mean:	20.86%		79.14%	

DISCUSSION

In today's era of modern medicine, the treatment of most patients is impossible without the use of any medical device. Despite the tough scrutiny and norms laid for the vigilance of adverse reactions due to drugs, there is a dire need for keeping a careful watch on the reactions and side effects caused by these devices. There have been various incidences and fatalities reported due to device mishaps.

Therefore, this study was done among the resident doctors who come in direct contact with the patients.

Evaluation of knowledge

The questionnaire comprised of 8 questions about the knowledge of materiovigilance, of which only 48.2% knew the ongoing programme in India for monitoring adverse events due to medical

devices which is comparable to the results seen in similar literature in the country. Moreover, an alarming 95.4% of the participants did not know about the correct categorisation of the devices. The study by Meher *et al.* suggested similar findings (88.6%),

Although our institute is a PvPI-registered ADR Monitoring Centre, there is no local institutional facility for reporting of ADRs due to medical devices available at present and hence adequate sensitisation of the residents should be done to impart accurate knowledge on the subject.

Evaluation of attitude

The assessment of attitude reflected an average score of 72.7% correct responses. The doctors understand their moral responsibility and 72.7% agree that they are obligated towards ADR reporting for overall well-being of their patients. 70% participants believe that reporting of any adverse events associated with the medical device is necessary. Other studies also revealed comparable findings.[4-6] This positive attitude was an encouragement to perform more such programmes for research in the future.

Evaluation of practice

The participants were assessed based on 6 questions for practice, where it was found that even though 38.6% doctors confirmed that they monitored the patients for any adverse outcome of implanted device, only 6.6% have reported the adverse events. This collaborates to results shown in similar studies by the other authors.

Moreover, currently, there is low awareness of the health facilities regarding the MvPI programme and its reporting mechanism, which needs to be developed further in active mode to address public health concerns related to Medical Devices. Therefore, it can definitely be emphasised from this study that there is a positive attitude towards MV, but there exists a wide gap in the knowledge and practice of ADR reporting for MV. This unmet need of MV should be catered to, which calls for regular sensitisation workshops and educational interventional programmes for the enhancement of Materiovigilance and ADR reporting in day-to-day practice. It should be inculcated as a part of the UG curriculum so that the residents are familiar to this concept while working during residency from the beginning [7-13].

Furthermore, this was a single-centric study so the number of participants was limited; and only postgraduate medical students were approached. Faculty, nurses and pharmacists can also report ADR but they were not included. This gives scope for further research in the area.

This research work is based on a newer concept in the region at the grassroot level of hierarchy and yet doctors from a variety of departments have responded which provides strength to this study.

CONCLUSION

Many PG students are aware of the term Materiovigilance, but they lack accurate knowledge about what should be done and regular practice of reporting needs to be developed. However, their positive attitude is a ray of hope for the future.

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AUTHORS CONTRIBUTIONS

All authors have contributed equally

CONFLICT OF INTERESTS

Declared none

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