

Awareness, attitude, and practice of materiovigilance among medical professionals at a tertiary care institute of national importance: A cross-sectional study

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Abstract

Background: Medical faculty and residents have a key role in the reporting of adverse events associated with medical devices. However, at present, there are no published data regarding their knowledge, attitude, and practice about materiovigilance in India.

Materials and Methods: This was a cross-sectional questionnaire-based survey done among medical faculty and residents of a tertiary care institution of national importance. The questionnaire consists of 15 questions pertaining to knowledge, attitude, and practice of materiovigilance.

Results: The questionnaire was administered to 138 medical faculty and residents, out of which 105 responded constituting a 76% response rate. The mean knowledge score of medical faculty and residents was 2.09 ± 1.06 and 2.07 ± 1.02 , respectively, and the difference between the two groups was not statistically significant ($P = 0.9$). The majority of the participants (92.63%) believed that medical device can cause adverse events; however, very few of them (20.13%) have reported it during their practice.

Conclusion: Requisite knowledge and appropriate attitude are essential for developing healthy practice toward reporting of adverse events associated with medical devices. Our study revealed that the knowledge gap exists among medical professionals about the reporting of adverse events and the materiovigilance program. A continuous effort is required to make them aware of the materiovigilance by conducting various training programs such as continuous medical education and workshops by the coordinators of the medical device adverse events monitoring center.

Keywords: Adverse events, adverse reactions, materiovigilance, medical devices

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INTRODUCTION

Medical devices play a vital role in the diagnosis, monitoring, and management of different diseases.^[1] Recognizing the increasing importance of medical devices in the health-care delivery, the World Health Organization has recommended an essential diagnostics list like that of essential medicines

list.^[2] A medical device is defined as any instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software, material or other similar or related article used for the diagnosis, prevention, treatment, or alleviation of disease.^[3] Medical devices can range from

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simple cotton bandage or syringe to heart pacemakers, coronary stents as well as complex instruments such as magnetic resonance imaging and software application.^[3]

Although medical devices benefit the patients by facilitating the diagnosis and management, the use of it is not entirely risk-free. Many times, medical devices use has caused morbidity and mortality in the device users.^[4] In the past, some devices such as breast implants, pacemakers, and hips prosthesis were recalled due to malfunction.^[5,6] It becomes essential to assess the risks and benefits during the premarketing development of the device as well as during its use through a robust-reporting mechanism. Materiovigilance is defined as the activities involving detection, collection, assessment, reporting, and prevention of any undesirable occurrences, resulting from the use of medical devices by a well-co-ordinated surveillance system.^[7]

Materiovigilance Program of India (MvPI) was launched in India on July 6, 2015 to create the awareness among the health care professionals about the importance of medical device-associated adverse events (MDAE) reporting and generate independent credible evidence-based safety data of medical devices.^[8,9] Although the program was launched nearly 4 years ago, we did not find any study regarding the awareness, attitude, and practice of medical professionals toward materiovigilance and factors influencing these behaviors; hence, we undertook this study.

MATERIALS AND METHODS

Study site

All India Institute of Medical Sciences, Bhubaneswar, India, a tertiary care institute of national importance.

Study design and Study population

This was a cross-sectional, questionnaire-based study designed to evaluate the knowledge, attitude, and practice of medical professionals working in an institute of national importance and using different types of implantable and other medical devices.

Ethical issue

The study was initiated after obtaining approval from the Institutional Ethics Committee. The medical professionals were approached, and given information about the study and those volunteered were included as participants.

Study tool

A 15-item structured survey tool was designed by the faculty members of the department of pharmacology. It consisted of two parts. The first part consisted of

questions about the demographic data of the medical professionals; the second part contained 15 questions about knowledge, attitude, and practice domain of materiovigilance. Content validity of the questionnaire was carried out by an expert panel who commented on the relevance, clarity, and simplicity of the questions. The reliability of the questionnaire was assessed by Cronbach's alfa ($\alpha = 0.74$). The study tool was pilot tested in 30 participants to assess appropriateness, relevance, and comprehensibility of questions. Then, the questionnaire was distributed to the participants, and their response was collected and analyzed. Knowledge was assessed by a scoring system. A score of 1 was allocated for each correct answer, whereas there was no negative score for the wrong answer. The mean knowledge score was calculated and compared between the two groups. Attitude and practice were assessed by closed-ended questions which can be answered by simple "yes or no."

Statistical analysis

All the data were entered into the Microsoft Excel sheet. Continuous data were expressed as mean \pm standard deviation, and categorical data was represented in proportions. The difference between the groups was assessed using the *t*-test for continuous data and Chi-square test for categorical data. Multiple regression analysis was carried out to assess the influence of age and designation of the medical professionals on the responses. The principal component analysis (PCA) was carried out to assess the factors influencing the responses. A sample size of 138 was required to produce a 95% confidence interval (CI) of 0.14 assuming that 20% of the respondents were aware of materiovigilance.

RESULTS

The questionnaires were distributed to 138 respondents, of which 105 (45 faculty, 60 residents) respondents returned the completely answered questionnaire (response rate approximately 76%).

It is evident from the study that only a few numbers of participants (26.7% faculty and 25 [41.7%]) knew about the program started by the Government of India to monitor MDAE ($P = 0.11$). The majority of the participants in this study knew that devices are classified based on the risk they carry; however, very few of them knew the category of devices. The mean knowledge score of medical faculty and residents was 2.09 ± 1.06 and 2.07 ± 1.02 , respectively. The difference between the two groups was not statistically significant [Figure 1]. Table 1 summarizes the response of participants toward knowledge-related questions.

Table 1: Summary of medical professional' knowledge about Materiovigilance

Item number	Knowledge-based questions	Correct response		P
		Group I Faculty (n=45), n (%)	Group II Residents (n=60), n (%)	
11	What is the ongoing program in India for monitoring adverse events due to medical devices?	12 (26.7)	25 (41.7)	0.11
12	What is the basis of classifying medical devices into different categories (A, B, C, D) in India?	32 (71.1)	44 (73.3)	0.801
13	Which of the following device belongs to category B?	9 (20)	3 (5)	0.017
14	Which of the following event need not be reported?	16 (35.6)	21 (35)	0.953
15	Where can an adverse event due to medical device can be reported?	22 (48.9)	35 (58.3)	0.336

P<0.05 was considered as statistically significant

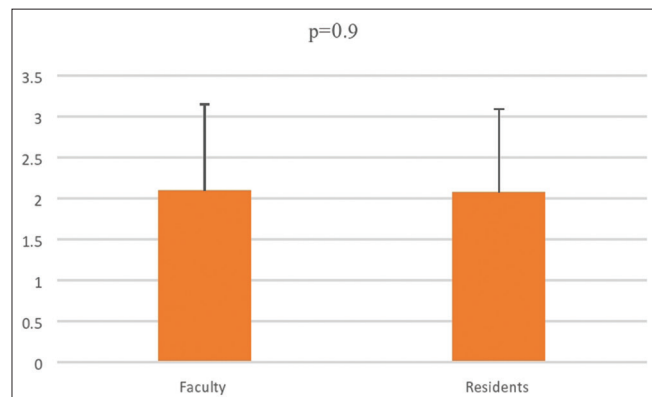


Figure 1: Bar diagram comparing the mean (±standard deviation) score of participants for knowledge-based questions. P <0.05 was considered as statistically significant

Attitude and practice of participants were assessed in this study by close-ended questions which can be answered with a “yes or no” response. It was observed that a large number of participants (38 [84.4%] medical faculty and 54 [90%] resident doctors) believed that medical device can cause an adverse event. A large number of participants (39 [86.7%] medical faculty and 56 [93.3%] resident doctors) also had the belief that doctors are obliged to report any adverse events occurs due to medical device. Table 2 sums up the response of participants to practice related questions.

As far as, the practice of participants in relation to materiovigilance is concerned many of them (25 [55.6%] faculties and 29 [48.3%] residents) expressed that they have encountered adverse events during their practice, but very few of them (6 [6.7%] faculties and 14 [3.3%] residents) have actually reported it. Table 3 encapsulates the response of participants towards attitude related questions, respectively.

Multiple linear regression did not reveal any significant influence of age ($\beta = 0.010, 95\% \text{ CI: } -0.066-0.086, P=0.78$) or designation ($\beta = -0.149, 95\% \text{ CI: } -0.566-0.268, P=0.48$) of participants on the responses.

The PCA identified four factors with eigenvalues >1. However, as factor 1 could explain 81.9% of total variance

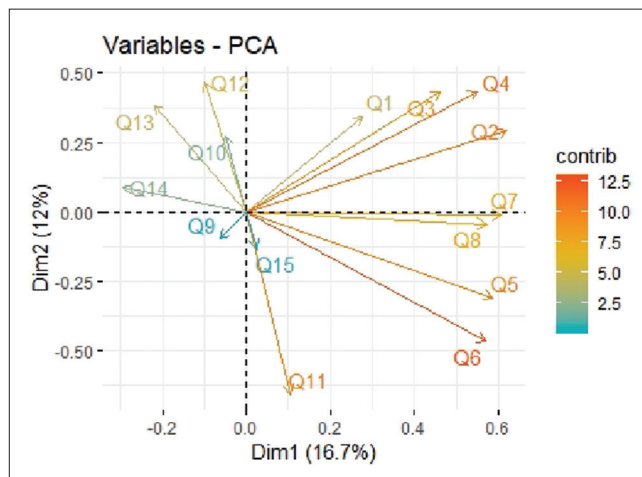


Figure 2: Principal component analysis showing the relative contribution of each question in our study. Questions 2, 4, 5, 6, 7, and 8 were major contributors, indicating their relative importance in determining the trend of responses in comparison to other questions of the questionnaire (contribution – percentage contribution)

with questions 2, 4, 5, 6, 7, 8 contributing to this factor, we retained it as our principal component [Figure 2].

DISCUSSION

Medical devices have been used for patient care for a long time. However, the concept of MDAE reporting is relatively new in India, and there is hardly any data available in the public domain regarding the awareness and attitude of medical professionals about materiovigilance.

Medical professionals who participated in this study had limited knowledge about the Materiovigilance. Many of them were not aware of the current MvPI initiated by the Government of India to monitor MDAE. Similarly, many of them had no idea where to report MDAE. Perhaps, it is because materiovigilance has not yet caught the imagination of medical professionals, unlike pharmacovigilance. A study was done in Romania also observed a similar finding.^[10] Underreporting of MDAE is common worldwide. According to the Food and Drug Administration, only 0.5% of adverse events associated

Table 2: Summary of medical professional' practice about materiovigilance

Item number	Practice-based questions	Response	Group I Faculty (%)	Group II Residents (%)	P
5	Have you ever encountered any adverse events due to medical device during your practice?	1	25 (55.6)	29 (48.3)	0.46
		2	20 (44.4)	31 (51.7)	
6	If yes, have you reported that?	1	6 (6.7)	14 (3.3)	0.42
		2	19 (93.3)	15 (96.7)	
7	Do you monitor the patients for any adverse outcome of implanted device beyond the recovery period?	1	14 (86.7)	27 (93.3)	0.57
		2	23 (13.3)	37 (6.7)	
8	Do you take any feedback for any untoward events from patients after implanting the device?	1	36 (80)	56 (93.3)	0.04
		2	9 (20)	4 (6.7)	
9	Have you seen the medical device adverse event reporting form prepared by CDSCO	1	9 (20)	9 (15)	0.50
		2	36 (80)	51 (85)	
10	Have you ever attended any workshop or CME focused on safety of medical device?	1	4 (8.9)	5 (8.3)	0.92
		2	41 (91.1)	55 (91.7)	

1=Yes, 2=No, $P < 0.05$ was considered as statistically significant. CDSCO=Central Drug Standard Control Organization, CME=Continuous Medical Education

Table 3: Summary of medical professional' attitude toward materiovigilance

Item number	Attitude based questions	Response	Group I Faculty (%)	Group II Residents (%)	P
1	Do you think medical devices can cause adverse events in the patient?	1	38 (84.4)	54 (90)	0.39
		2	7 (15.6)	6 (10)	
2	If yes, do you think reporting of any adverse events associated with the medical device is necessary?	1	42 (93.3)	58 (96.7)	0.42
		2	3 (6.7)	2 (3.3)	
3	Do you agree it is the obligation of doctors to report adverse events due to medical device?	1	39 (86.7)	56 (93.3)	0.23
		2	6 (13.3)	4 (6.7)	
4	Do you think reporting of adverse event will enhance patient safety?	1	36 (80)	56 (93.3)	0.04
		2	9 (20)	4 (6.7)	

1=Yes, 2=No, $P < 0.05$ was considered as statistically significant

with the device are reported.^[11] A similar trend was noticed in this study as well where only 3.3% of medical professionals had ever reported an adverse event related to the device. It must be emphasized that physicians are more inclined to report adverse events with drugs compared to devices. Pane *et al.* have attributed this differential reporting to ill-defined regulatory medical device surveillance guidelines, poor reporting mechanisms, and the absence of global or national databases to collect and analyze adverse events due to medical devices. They also identified that various aspects of the pharmacovigilance program can be adopted to strengthen the materiovigilance program.^[12]

Despite poor knowledge, participants in this study showed a positive attitude toward MDAE. The majority of them perceived that medical device can cause adverse events and reporting of those events will enhance patient safety. A similar positive attitude for adverse events reporting associated with medical devices was observed in a study done by Kurien *et al.*^[13] However, Gagliardi *et al.* observed contrarian attitude, they had found that medical professionals considered reporting of adverse events associated with medical devices as unnecessary and pointless. They also did not perceive the reporting of adverse events as their responsibility.^[14]

The practice of adverse event reporting among the participants of our study is extremely poor. Many of them

neither attended any training program related to adverse event reporting nor reported any adverse events. This could be due to the lack of awareness and proper reporting system. In a study done by Gagliardi *et al.*, medical professionals cited multiple factors such as lack of proper reporting system, absence of a conducive environment as some of the barriers for the practice of materiovigilance.^[14] There was no influence of the age or designation of participants on the responses. Therefore, we believe that reporting culture among the medical professionals might improve, irrespective of age or designation, if their awareness is enhanced by interventions like Continuous Medical Education, workshop and other training programs. A study done by Coyle *et al.* found that early exposure of postgraduate medical trainees to the medical education program for medical event reporting had positively affected their reporting attitude.^[15]

The answering pattern for the questionnaire was analyzed by PCA. PCA provided us four major factors. However, factor 1 could explain nearly 82% of the total variance. The questions 2, 4, 5, 6, 7, and 8 were contributors to this factor with Q 2 and 7 being the two most important contributors. This factor seems to be related to the attitude of the doctor towards reporting of adverse events with medical device which in turn drives the practice, i.e. doctors who believe that reporting of adverse events is necessary as it can enhance patient safety are more likely to monitor, detect

and actually report adverse events (if encountered) in their patients. This is a rather important finding of our study as it indicates that the medical professionals in our institute would adopt a targeted, well designed materiovigilance program with relative ease.

The strength of this study that PCA was performed to analyze the trend of response. The weakness of our study was that it was conducted in only one institute with a small population of medical professionals which may not be the correct representation of all medical professionals across the country.

CONCLUSION

We conclude that the awareness and practice of materiovigilance among medical professionals of our tertiary care hospital are inadequate. However, their positive mindset toward adverse event reporting is reassuring. To promote the adverse events, reporting practice among medical professionals' proper educational intervention is necessary.

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Conflicts of interest

There are no conflicts of interest.

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