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Research Article

A QUESTIONNAIRE-BASED STUDY TO ASSESS THE AWARENESS OF MATERIOVIGILANCE AMONG HEALTH-CARE PROFESSIONALS WORKING IN A TERTIARY CARE TEACHING HOSPITAL IN THE KURNOOL DISTRICT

SANGALA SRIMANTH MANDANNA, SURESHA KR*, NARAYANA REDDY S, SAMBA SIVA RAJU

Deparment of Pharmacology, Viswabharathi Medical College, Kurnool, Andhra Pradesh, India.
***Corresponding author: Dr. Suresha KR; Email: drsuresh_pharmac@rediffmail.com**

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ABSTRACT

Objectives: Materiovigilance (MV) is the coordinated system of identification, collection, reporting, and analysis of untoward occurrences associated with the use of medical devices (MD) and enhancing patients safety, also preventing their recurrence by health-care professionals (HCPs). The HCPs have a key role in the identification and reporting of adverse events associated with MD for continued patient safety.

The aim of the study is to assess awareness of the recently launched MV Programme in India among the health-care professionals working in a tertiary care teaching hospital.

Methods: A questionnaire-based study was conducted among health-care professionals of Viswabharathi Medical College and General Hospital, like residents, interns, nurses (OT, emergency, intensive care unit, etc.), and laboratory technicians of various specialties working in a tertiary care teaching hospital in Kurnool. A pre-validated questionnaire consisting of questions pertaining to knowledge, attitude and practice of MV was circulated to HCPs through Google Forms, and data were recorded and analyzed using statistical tests.

Results: One hundred and eighteen doctors responded out of 200 contacted, providing a response rate of 59%. They belonged to medical and allied branches (77), surgical branches (24), and diagnostic branches (17). Sixty-nine (58.5%) doctors strongly agreed that these types of programs are very effective in keeping a check on AE caused by MD. 98 (83%) doctors responded-certainly; we should report all the AEs.

Conclusion: This study creates awareness about MV and imparts a reporting culture among the HCPs.

Keywords: Medical devices, Materiovigilance, Health care professionals, Adverse events.

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INTRODUCTION

Materiovigilance (MV) is the coordinated system of identification, collection, reporting, and analysis of untoward events associated with the use of medical devices (MD) [1]. MD plays a vital role in the diagnosis, monitoring, and management of different diseases and conditions [2]. Recognizing the increasing importance of medical device usage in health care delivery, the World Health Organization has recommended an essential diagnostics list like that of essential medicines list [3]. Today, we have more than 1 million MDs available, ranging from simple bandages to complex devices such as magnetic resonance imaging, etc. [4].

MD not only provides immense benefit to patients but it has also extended the ability of clinicians to diagnose and treat various disease conditions [5]. However, after several cases of malfunctioning devices, like babies being burned to death due to short circuits in incubators or hip implants causing malunion, septicemias, etc., it has become important to keep a check on the functioning of MD and report any untoward event associated with it [6].

The government of India has approved the MV Program in India (MvPI) to monitor MD adverse events (MDAEs), create awareness among health-care professionals about the importance of MDAE reporting, and generate independent, credible evidence-based safety data with the usage of MD [7,8].

In the past few years, there has been an increased focus on quality and safety studies with MDs in India [9]. From the start of MvPI to October 2019, adverse effects associated with cardiac stents were the most commonly reported, with 926 events (47.95%), followed by IUCD and orthopedic implants [10]. The present study was conducted to assess awareness of the recently launched MvPI among health-care professionals working in a tertiary care teaching hospital.

METHODS

A cross-sectional questionnaire-based study was conducted at a tertiary care teaching hospital in Kurnool from April 2023 to May 2023 among health care professionals (HCPs) (postgraduates, internees, nurses, and technicians).

The questionnaire was developed after an extensive review of the literature available related to MV [11,12]. A questionnaire format was made, comprising four sections:

1. Personal details
2. MV Knowledge
3. Attitude towards adverse events (AEs) report
4. Actual practice of AEs reporting

The final questionnaire comprised of 30 questions divided into four sections. Section 1 had three questions related to personal details and consent; Section- 2 had nine questions regarding knowledge of MV; Section- 3 had nine questions related to attitude toward MV; and Section- 4 had nine questions related to practice.

The questionnaire was converted into a Google form and circulated through email or online messaging apps. A reminder call was made

to those who did not respond even after one week. After 15 days, acceptance of responses was stopped.

Statistical analysis

All the data were entered into the Microsoft Excel sheet. The data is expressed in numbers and percentages. Continuous data were expressed as mean ± standard deviation, and categorical data was represented in proportions. The difference between the groups was assessed using the *t*-test for continuous data and the chi-square test for categorical data.

Ethical considerations

The research protocol and questionnaire-based study were approved by the Institutional Ethics Committee (IEC/PHARMA/VBMC/01/2023).

RESULTS

Four hundred and five (405) health-care professionals responded out of 570 contacted, providing a response rate of 71%. 85 were postgraduates, 115 were internees, 160 were nurses, and 45 were technicians (Fig. 1).

Knowledge about MV

Questions related to knowledge about MV were asked. Table 1 shows the percentage of responses given by participants.

Attitude of MV

66 (77%) postgraduates and 86 (74%) internees strongly agreed MD can cause AEs in patients. 98 (84%) internees responded that reporting any AEs associated with the medical device is necessary. 76 (89%) postgraduates responded that it is a health care professional responsibility to report every medical device-induced AE. 80 (94%) postgraduates and 106 (91%) Internees responded that medical device-induced AE reporting should be mandatory. 84 (98%) postgraduates responded that MV should be taught in detail to HCPs. 114 (98%) internees responded that reporting medical device-induced AEs can improve patients' safety and so must be encouraged, as shown in Table 2.

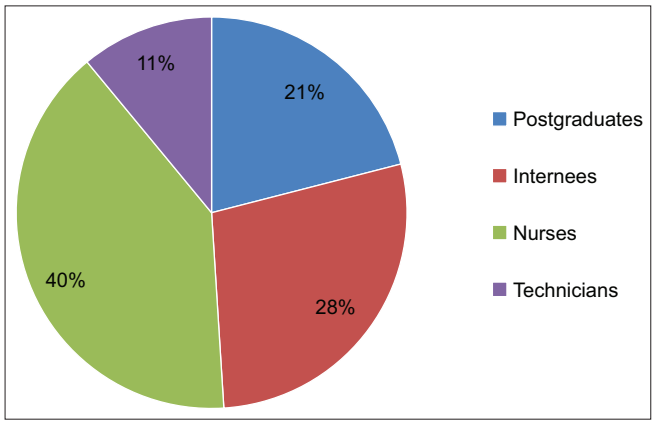

Fig. 1: Description of the study sample

The practice of reporting AE

37 (82%) technicians responded that they have come across patients experiencing AEs with usage of MD. 54 (63%) postgraduates responded that they have read articles on the consequences of AEs due to medical device. 43 (50%) postgraduates responded that they have free access to the MD AEs reporting form. 76 (89%) postgraduates and 134 (83%) nurses responded that they monitor the patients for any adverse outcomes of MDs beyond the recovery period, as shown in Table 3.

DISCUSSION

A well-formed vigilance system is the backbone of post-marketing surveillance of MDAE, and health-care professionals play a key role in the reporting of AE. Hence, it is important to know about the knowledge, attitude, and practice of health-care professionals regarding MV in a tertiary care teaching hospital. We got a response rate of 71% in our study. Although more than half of the participants heard the term MV for the first time during the conduct of this study, still two-thirds gave the correct definition of MV. This is one of the key findings of our study. Knowledge about the process of reporting is found to be lacking. Although the outlook of medical professionals is positive, a gap between the AEs observed and the practice of reporting is found.

Health-care personnel play an important role in the reporting of AEs, so they should be well versed in the process of reporting events. This is possible by conducting education programs to increase knowledge about MV. A positive attitude among medical professionals similar to our study was also found in the study done by Meher *et al*. and Kurien *et al*. [7,13] A gap between observation and reporting of AE was similar to the results published by the FDA and a study done by Meher [7,14] The problem of underreporting is worldwide, even for ADR in countries where pharmacovigilance (PV) programs are well established, like the UK [15-18]. The common problem with the vigilance programs has been found to be underreporting [19,20]. Some of the MDs have also been classified as drugs. So, it becomes important that PV and MV should go hand in hand. Thus, there is a need to find out the reasons behind under-reporting of PV as well as MV and work efficiently to mitigate them. According to some studies, professionals understand the importance of reporting and want to report, but a lack of knowledge becomes the limiting factor. Others believe that it is not their responsibility to report AE due to drugs or MD [21].

Table 1: Knowledge about Materiovigilance among health-care professionals as percentage of correct responses

Questions	Post graduates (n=85; 21%), n (%)	Internees (n=115; 28%), n (%)	Nurses (n=160; 40%), n (%)	Technicians (n=45; 11%), n (%)
1. Do you know what MV is?	65 (76)	75 (65)	45 (28)	10 (22)
2. Are you hearing MV for the 1st time?	20 (24)	40 (35)	115 (72)	35 (78)
3. What are the commonly used MDs in your practice?	45 (53)	75 (65)	105 (66)	25 (56)
4. Do you know even MDs can cause adverse events?	63 (74)	84 (73)	76 (47)	12 (27)
5. Do you know where to report adverse events occurring due to MDs?	40 (47)	25 (22)	32 (20)	10 (22)
6. Have you seen MD adverse event reporting form prepared national coordinating centre MV program of India?	25 (29)	36 (31)	12 (8)	5 (11)
7. Do you know who can report MD adverse event?	81 (95)	89 (77)	43 (27)	16 (36)
8. Do you think reporting of adverse event will enhance patient safety?	76 (89)	110 (96)	107 (67)	28 (62)
9. Is it mandatory to have MV unit in every medical college?	83 (98)	98 (85)	105 (66)	29 (64)

MDs: Medical devices, MV: Materiovigilance

Table 2: Attitude about materiovigilance among health-care professionals as percentage of correct responses

Questions	Postgraduates (n=85; 21%), n (%)	Internees (n=115; 28.4%), n (%)	Nurses (n=160; 39.6%), n (%)	Technicians (n=45; 11%), n (%)
1. Do you agree MDs can cause adverse events in the patients?	66 (77)	86 (74)	78 (48)	17 (38)
2. If yes, do you think reporting of any adverse events associated with the MD is necessary?	58 (68)	98 (84)	106 (66)	26 (58)
3. Do you think it is a health care professional responsibility to report every MD induced adverse event?	76 (89)	87 (75)	113 (70)	11 (24)
4. Do you think MD induced adverse event reporting should be mandatory?	80 (94)	106 (91)	76 (47)	23 (51)
5. Are you willing to report a MD induce adverse event?	78 (91)	107 (92)	146 (91)	42 (93)
6. Should MV be taught in detail to Health care professionals?	84 (98)	108 (93)	151 (94)	39 (87)
7. Do you agree that reporting of MD induced adverse events can improve patient's safety and so must be encouraged?	76 (89)	114 (98)	126 (78)	31 (69)
8. Do you agree it is the obligation of health care professionals to report adverse events due to MD?	75 (88)	10 (90)	97 (60)	26 (58)
9. Do you think MV will generate evidence based data regarding safety of devices which are already marketed and are in day today practice?	81 (95)	96 (83)	89 (55)	17 (38)

MDs: Medical devices, MV: Materiovigilance

Table 3: Practice about materiovigilance among health-care professionals as percentage of correct responses

Questions	Postgraduates (n=85), n (%)	Internees (n=115), n (%)	Nurses (n=160), n (%)	Technicians (n=45), n (%)
1. Have you ever come across a patient experiencing adverse events with the usage of MD?	43 (50)	37 (32)	87 (54)	37 (82)
2. Have you ever read any articles on the consequences of adverse event due to MD?	54 (63)	32 (27)	23 (14)	12 (27)
3. Do you have free access to MD adverse event reporting form?	43 (50)	46 (40)	27 (17)	16 (35)
4. Have you ever been trained on how to report an adverse event due to MD?	3 (3.5)	4 (3.4)	0	0
5. Do you know about helpline number to report MDAE?	3 (3.5)	5 (4.3)	1 (0.62)	1 (2.2)
6. Do you expect feedback from MD adverse events monitoring centers?	56 (65)	78 (67)	81 (50)	21 (47)
7. Do you monitor the patients for any adverse outcomes of MDs beyond the recovery period?	76 (89)	84 (72)	134 (83)	29 (64)
8. Do you take any feedback for any untoward events from patients after usage of MD?	23 (27)	32 (27)	44 (27)	12 (27)
9. Are you feeling in your practice that strict vigilance of MD is needed to eliminate substandard/counterfeit MD from the market?	82 (96)	110 (95)	126 (78)	37 (82)

MDs: Medical devices, MDAE: MD adverse event

CONCLUSION

Our study concluded that the health-care providers have moderate knowledge and a positive attitude toward MV and MDAE reporting, but, unfortunately, the actual practice of MDAE reporting is still deficient among them. There is a need to conduct various educational and training programs to improve reporting practices, thereby contributing to the safety of MD usage.

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