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Original Research Article

Knowledge, Awareness and Practice of Materiovigilance among Healthcare Professionals in a Tertiary Care Hospital of Eastern India: A Cross-Sectional Observational Study

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Abstract

Background: Medical devices are an essential part of modern health care. Despite that there are instances where their uses caused significant morbidity and mortality in the users. So, it is necessary to assess the risk and benefit associated with devices at all stages of development and uses. Materiovigilance is the coordinated system of identification, collection, reporting, and analysis of any untoward occurrences associated with the use of medical devices. Although medical faculties and residents are major stake holders in reporting adverse events related to medical devices at present there are very few published data about their knowledge attitude and practice regarding materiovigilance in India. This study was conducted with an objective to assess the knowledge, attitude and practice of materiovigilance amongst the doctors in a tertiary care teaching hospital of Eastern India.

Methodology: This is a cross-sectional questionnaire based observational study. The questionnaire containing 15 questions is made in Google forms and were distributed to all the doctors of this hospital. Among 135 doctors, 125 doctors have answered and the recorded responses have been statistically analysed.

Results: Among the responders approx. 74% were not aware of the ongoing program for monitoring adverse events due to medical devices. Despite 46.8% responders facing adverse events relating to medical devices 32.5% of participants have actually seen the reporting form and only 18.4% reported the events.

Conclusion: More awareness drive is needed to fulfil the lacunae in the knowledge regarding adverse events related to medical devices

Keywords: Materiovigilance, Doctors, MvPI, Medical Device Related Adverse Events, Patients.
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Introduction

A medical device is any tool used in helping individuals or animals for disability management or diagnosis, prevention and treatment of any disease [1]. The term “medical device” has been defined by the World Health Organization as “Any instrument, apparatus, reagent for in vitro use, implant, device for tissue cutting or wound covering, highly sophisticated computerised medical equipment software or other related or similar materials which are intended to be used for diagnosis, prevention treatment and monitoring of diseases” [2].

Medical devices are life-saving tools that can range from a simple cotton bandage to hip implants. [3] Some of the most frequently used medical equipment involve pacemakers, contraceptives, incubators, artificial hip implants [4]. The medical devices have been classified by United States Food and Drug Administration (USFDA), Therapeutic Goods Administration (TGA) and Medicines and Healthcare products Regulatory Agency (MHRA) [5]. First medical device associated adverse event came into light in 2002, when a 60-year-old man received his first implantable cardioverter defibrillator and later, the communication with ICD was lost and the patient experienced multiple shocks via electrocardiogram telemetry every time the doctors tried to communicate.

A pharmaceutical company, back in 2010, had to withdraw their hip implants due to serious adverse event of friction by the wearing of prosthetic ball and socket and release of metallic particles into the blood stream. Failure of spinal cord stimulator was

observed in a 45-year-old patient in 2014 who could not sleep and could hardly move. The FDA has been reporting several such cases since 2008. In this regard, due to the uprise in such events, The Health Ministry of India, set up an expert committee for the evaluation of these issues [6] & called for the strict presence of a vigilance system to regulate such incidents. [7][8][9] Materiovigilance deals with the identification, collection, reporting, estimating the undesirable occurrences and the possible management of adverse events associated with the use of medical devices thus promoting patient health by preventing its recurrences [11].

The Materiovigilance programme of India (MVPI) was approved by the Ministry of Health and Family Welfare on 10th February, 2015 and was launched on the 6th July 2015 by the Drug Controller General of India at Indian Pharmacopoeia Commission, Ghaziabad, India [12]. Any sort of adverse events can be reported through the adverse event reporting form, created by the MvPI, available in the official website of IPC, to the coordinator of MDMC or directly to the national collaborating centre. The reporter can also report by sending an email or by calling the toll-free helpline number. [15] Although, there has been a marked increment in the reporting of adverse event associated with medical device in India from only 40 events in 2015 to 897 events in 2019, but still this is much less compared to 5348 adverse events reported under Australian Regulatory Authority in 2017-2018 [7].

Thus, this study was conducted with an objective, to assess the knowledge, attitude and practice of materiovigilance among healthcare professionals in a tertiary care teaching hospital of eastern India.

Materials and Methods

This is a questionnaire based cross-sectional observational study conducted among all the doctors of Medical College Kolkata including the junior residents and house staffs. It was conducted between February 2025 to May 2025.

After receiving the approval from the Institutional Ethics Committee of Medical College Kolkata the study was initiated. Participation was voluntary and it was conducted after receiving proper written consent from the participants. The study participants were assured of the confidentiality of the data and their identity. They were also briefed about the rationale of the study.

Initially a structured questionnaire was prepared in English which was administered via google forms. The initial version was pilot tested among 20 randomly selected doctors of other medical colleges of Kolkata and was checked for appropriateness. A structured and prevalidated questionnaire was prepared which was approved by the Institutional Ethics Committee.

The questionnaire comprised of 15 questions and all were either closed ended or multiple-choice questions. There were 6 questions assessing the knowledge of the study participants and 4 questions related to attitude and 5 of practice. The study participants were requested to provide their answers in “yes or no” format or tick one answer in case of multiple choices. The questionnaire was distributed to the participants via a digital web link using various social media platforms and emails and their responses were collected. The responses were entered into Microsoft Excel sheet. For statistical analysis, statistical package for Social Sciences software version 29 was used & presented in numbers & percentages.

Table 1: Questionaries on Materiovigilance knowledge, Attitude& Practice.

Knowledge		
1.	Are you aware of the term materiovigilance?	Yes/No
2.	Are you aware of the existence of Materiovigilance Programme of India (MVPI)?	Yes/No
3.	Are you aware of the reporting centre of medical device related adverse events?	Yes/No
4.	Do you know the location of the national coordinating centre of MVPI?	Yes/No
5.	Have you seen the medical device adverse event (MDAE) reporting form?	Yes/No
6.	Who can report medical device related adverse events?	Doctors/Nurses/Medical device manufacturers/ All of the above
Attitude		
1.	Is reporting of MDAE mandatory?	Yes/No
2.	Will the reporting of MDAE benefit patient care?	Yes/No
3.	Is it necessary to make your patients aware regarding MDAE?	Yes/No
4.	Is there any need for periodically conducting workshops on MVPI in the institute?	Yes/No
Practice		

1.	Did you face any adverse event due to medical device during your practice?	Yes/No
2.	If yes, did you report?	Yes/No/Not applicable
3.	Have you been trained in filling up of MDAE forms?	Yes/No
4.	Have you monitored your patients about adverse event due to medical device past their recovery?	Yes/No
5.	Have you made your patients aware about the adverse events that may be associated with the use of medical devices?	Yes/No

Results: Out of a total of 135 questionnaires distributed, 125 were completed and returned and a response rate of 93.3% was obtained.

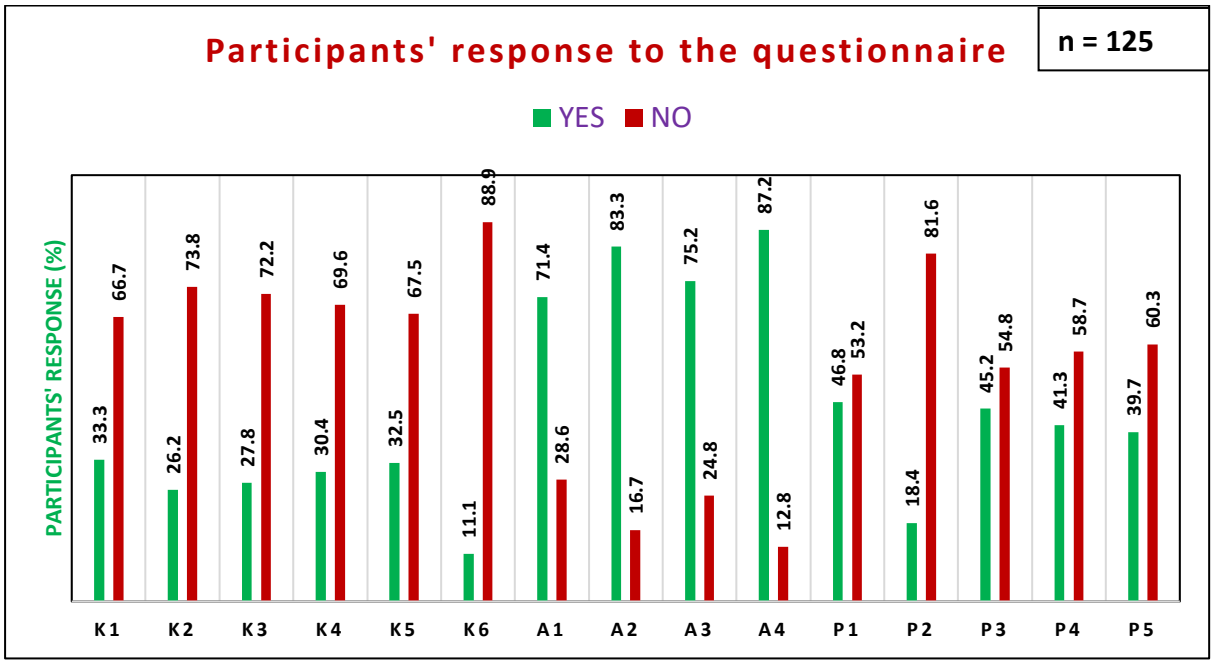

Figure 1: Questionaries on Materiovigilance knowledge, Attitude& Practice

Participant's knowledge about materiovigilance: About 33.3% (42) of them were aware about the term materiovigilance and 26.2% (33) of them were actually aware about the existence of Materiovigilance program of India and 27.8% (35) were aware of the functioning of medical device related adverse event (MDAE) reporting centre. 30.4% (38) have the knowledge about the location of national collaborating centre of MvPI. Only 11.1% (14) had the knowledge regarding who can report about the MDAE. Only 32.5% (41) of them have actually seen the MDAE reporting form. Based on the overall knowledge level very few doctors had adequate knowledge and awareness regarding this.

Participant's attitude towards materiovigilance: Majority of them considered it to be mandatory to report any sort of adverse event related to medical devices. 83.3% (105) of them considers that the reporting of adverse event would benefit patient care. Almost 87% (109) of them were of the opinion that it is necessary to conduct educational meets via seminars and workshops to enhance their knowledge and practice on materiovigilance through searches in internet and reading original articles. 71.4% (90) of the doctors considers it mandatory to report the adverse events and almost 75% (94) of the doctors considers it necessary to make the patients aware regarding adverse events associated with medical devices.

Participant's current practice of materiovigilance: Around 46.8% (59) of the doctors faced untoward occurrences related to medical devices among their patients during practice but very few of them 18.4% (23) have actually reported about the MDAEs. There is a poor practice of MDAE reporting observed among the doctors of this tertiary care hospital.

Only 39.7% (50) of them have made their patients aware about the adverse events that may occur with the use of medical devices. It is evident from the study that only 41.3% (52) of the doctors have monitored the patients for adverse outcome of the implanted device beyond their recovery period. Among them only 45.2% (57) of them have been trained to fill the MDAE forms.

Discussions

Medical devices have been in use for a long time to benefit patient care. However, with the upsurge in the use of medical devices there also has been an increase in the untoward occurrences. There are very few data available on the knowledge attitude and practice of materiovigilance among doctors in India.

A study conducted by Teow et al showed under reporting by practitioners. Only 3% of practitioners are observed to file a report on adverse event due to medical devices. Although a higher response rate of 93% was observed in this study [16].

Health care professionals who took part in this study had inadequate knowledge about materiovigilance. Majority of them were unaware of the ongoing programme on materiovigilance of India. A study conducted on nursing professionals by Alsohime et al showed inadequate knowledge and reporting on the untoward occurrences associated with medical devices [17].

Despite poor knowledge regarding materiovigilance, our study showed a positive attitude towards MDAE. The majority of them considered it to be mandatory to report these events and benefit patient care. Similar positive attitude was seen in a study conducted by Kurien et al [18].

However, a study conducted by Gagliardi et al observed a completely opposite attitude [19]. They did not perceive the reporting of adverse event due to medical device to be necessary for benefit of patient care.

In a study conducted by Meher et al only 40% of the respondents were acquainted about the ongoing programme on materiovigilance and 65% of them were not aware of the procedure of reporting of MDAE and was unaware of where to report. 65% of the respondents in spite of encountering with the malfunctioning of devices and untoward occurrences most of them have not reported these events. 79% of the respondents also did not see the MDAE form [20]. In another previous study conducted by Meher et al in spite of the fact that many of them experienced adverse events during their practice, very few of them actually reported it. In our study also we found that there is extremely poor practice of adverse event reporting among the doctors [21].

In a study done by Coyle et al it was observed that medical event reporting has increased positively through medical education programme [22]. In our study we found that the participants have a positive attitude to enhance their knowledge through educational meets and to increase their awareness. They also considered it necessary to conduct regular programmes on Materiovigilance to enhance their knowledge and practice.

Therefore, we are of the opinion that the culture of reporting might escalate among medical professionals through training programmes.

The strength of our study is that we could analyse the pattern of responses among the doctors. The weakness of study lies in that it is conducted in only one institute with very less sample size which may not correctly represent the entire medical professionals across the study. Another limitation is that the nursing professionals who are one of the major stakeholders are not included in this study.

In the present study it has been observed that the doctors of a tertiary care teaching hospital of Eastern India are lacking proper requisite knowledge on multiple aspects of materiovigilance. Although there is a positive attitude towards materiovigilance but there is a lack of good practice of medical device related adverse event reporting among the study participants. Hence with due considerations of these lacunae regarding knowledge attitude and practice of materiovigilance among doctors, there lies adequate need for sensitisation by proper educational interventions through conducting periodical workshops, seminars and training sessions to enhance their reporting and thus benefit patient healthcare and services.

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