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IP International Journal of Comprehensive and Advanced Pharmacology

Journal homepage: https://www.ijcap.in/

Original Research Article

Materiovigilance: Impact of awareness cum sensitization programme on healthcare professionals of a tertiary care teaching hospital in South Delhi

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ARTICLE INFO

Article history:
Received 16-07-2022
Accepted 25-07-2022
Available online 23-08-2022

Keywords:
Materiovigilance
Medical devices
Adverse events
Awareness programme

ABSTRACT

Background: Medical devices play a significant role in the diagnosis, monitoring, and management of different health disorders or conditions. Healthcare professionals play a significant role in the medical device adverse events reporting. However, there are only few studies regarding the awareness of medical professionals toward materiovigilance and thus, the study is to evaluate the impact of awareness cum sensitization programme towards Materiovigilance on healthcare professionals of a tertiary care teaching hospital in south Delhi.

Materials and Methods: This was a cross-sectional questionnaire-based study done among the nursing professionals of a tertiary care teaching institute, South Delhi to evaluate their knowledge towards materiovigilance. The questionnaire consists of 10 questions. An Awareness cum Sensitization was organised to sensitize them towards MvPI. The study questionnaire were distributed to all the participants before and after the session and collected within 10 minutes. Responses were analysed.

Results: The questionnaire was distributed to 31 nursing professionals of various departments. Most of the nursing staff (16.12%) were from neonatal Intensive Care Unit (NICU). Many of them gave correct responses even before training but there is marked improvement in the knowledge of the nursing professionals towards materiovigilance after the training session as evident by their correct responses post training.

Conclusion: Appropriate knowledge of materiovigilance is required to report adverse events associated with medical devices. Our study showed that health care professionals of our institute is lacking in their knowledge of materiovigilance. However, awareness programme on materiovigilance is helpful in improving the knowledge and also motivated them to report MDAEs with full enthusiasm.

1. Introduction

According to WHO, a medical device can be defined as any instrument, apparatus, implement, machine, appliance, implant in-vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for the diagnosis, prevention, treatment, or alleviation of disease.[1] They can vary from the simple cotton bandage or injection syringes to the pacemakers, implants and also include the complex devices such as Computed Tomography Scan[1] Medical devices play a significant role in the diagnosis, monitoring, and management of different health disorders or conditions.[2] After recognising the growing importance and usage of medical devices in the health-care system, WHO (World Health Organization) has released an essential diagnostics list similar to that of EML (essential medicines list).[3] Despite the fact, medical devices provide benefit to the patients, its use is not completely devoid of risk. It can cause morbidity and mortality in

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https://doi.org/10.18231/j.ijcaap.2022.030

the patients or users of medical device.[4] Many medical devices like catheters, infusion pumps were recalled due to malfunction since these may cause serious injuries or death.[5,6] Therefore, it is very important and crucial to analyse the benefit-risk ratio of medical devices and to generate evidence based information on safety of medical devices during the premarketing development phase of the medical devices as well as during its use through an appropriate reporting process. Materiovigilance is the close monitoring of any undesirable performance or characteristics fluctuations of a medical device by means of a system which is capable of identifying, collecting, reporting and reacting to them with field safety corrective actions or device recall during post - marketing phase of a Medical Device.[7] The Ministry of Health and family Welfare (MoHFW) has approved commencement of "Materiovigilance Programme of India (MvPI)" on 2015 in an effort to ensure safety of medical devices and also to generate awareness among health care professionals towards the importance of reporting of medical device-associated adverse events (MDAE) and thereby establishing reliable evidence-based safety data of medical devices.[8] Despite the fact, the program has been started 7 years ago, we found only few studies regarding the awareness of medical professionals toward materiovigilance and therefore, the objective of the present study is to evaluate the impact of awareness cum sensitization programme towards Materiovigilance on healthcare professionals of a tertiary care teaching hospital in south Delhi.

2. Materials and Methods

2.1. Study site

Hamdard Institute of Medical Sciences & Research, New Delhi, India, a tertiary care teaching institute.

2.2. Study design and study population

This was a questionnaire-based study designed to evaluate the knowledge of nursing professionals working in Hamdard Institute of Medical Sciences & Research and associated HAHC hospital. A total of 31 nursing professionals from different medical and surgical disciplines were enrolled in the study in the month of June 2022. Only the healthcare professionals who has given the consent to participate were included in the study.

2.3. Study tool

There was a 10-item structured survey tool which was designed by the faculty members of the department of pharmacology. The questionnaire was designed based on earlier studies for assessing knowledge of medical device adverse event reporting.[9] It consisted of two parts. The first part consisted of questions about the profession and department details; the second part contained 10 questions about knowledge regarding materiovigilance. Their identity were held in strict confidence to the fullest extent. An Awareness cum Sensitization Program on "Importance of Materiovigilance and Reporting of Medical Device Adverse Events" was organised for the nursing professionals on 21st June 2022 by the Medical Device Monitoring Centre, Department of pharmacology, HIMSR and associated HAHC hospital to sensitize them towards MvPI. Data was collected twice, both pre-training and post training to determine areas of improvement and loopholes in our training session. It also helps us to measure our training program's efficiency. A total of 31 questionnaires were distributed and the nursing professionals were requested to fill and return them within 10 minutes before training and after training. Data collection for this study began on June 21, 2022 and was completed by June 21, 2022. After collecting the data, responses were analyzed. Assessment was done by scoring system. A score of 1 was given for each correct answer, whereas there was no negative scoring for the wrong responses. The scores were then calculated and compared between the two groups i.e., pre-training and post training.

2.4. Statistical analysis

All the responses which we received from the returned questionnaire were entered into the Microsoft Office Excel 2019 and analyzed as percentage.

3. Results

An awareness cum sensitization program regarding Materiovigilance was held on 21stJune 2022 and was attended by the 31 nursing professionals from the different departments of the hospital. The study questionnaire were distributed to all the participants before and after the session. All the participants has filled the questionnaire. Majority of the nursing staff (16.12%) who attended the session were from neonatal Intensive Care Unit (NICU) followed by nursing staff from the labour room and orthopaedic ward (9.67%). 12.9% of nursing staff were from the private ward and medicine ward. 6.45% of nursing professionals were from different departments such as Gynaecology, Surgery Ward and Operation Theatre (OT). 3.22% of nursing staff were from Surgical ICU, ENT Ward, Central Sterile Supply Department (CSSD), Emergency, Paediatric Ward and Paediatric ICU. Figure 1 summarizes the percentage of nursing participants from different departments.

We have done the comparative analysis of pre training and post training responses of the participants who attended the Awareness cum Sensitization Program. 90.3% of nursing professionals were already aware about the

Table 1: Responses of the nursing participants regarding the materiovigilance pre and post training session

Question No .	Knowledge based question	Pre training correct responses		Post training correct responses	
		(n=31)	n (%)	(n=31)	n (%)
1	What is Materiovigilance program of India?	28	90.3	31	100
2	What is the full form of MvPI?	18	58.0	31	100
3	What is the full form of MDMC?	30	96.7	31	100
4	Which department is centre for Reporting of Medical device adverse event in HIMSR?	19	61.2	31	100
5	Who can report medical device adverse event?	31	100	31	100
6	Reporting of Medical device adverse event for healthcare professionals should be voluntary or mandatory?	28	90.3	30	96.7
7	Where to report Medical device adverse event?	28	90.3	30	96.7
8	Reporting of medical device related adverse events is not my responsibility as far as my job profile is concerned or my professional as well as ethical responsibility?	31	100	31	100
9	Reporting of medical device adverse events to MvPI can attract legal complications from regulatory authority or make a contribution towards a meaningful outcome?	19	100	28	90.3
10	What are the benefits of MvPI?	31	100	31	100

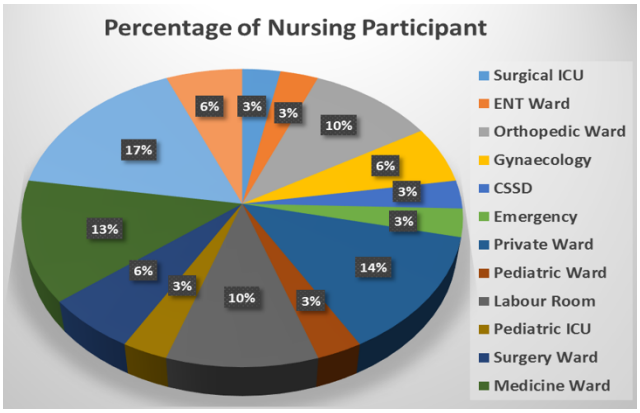

Fig. 1: Department wise distribution of participants

Materiovigilance programme of India which has increased upto 100% after the training session. Less than 58% of participants were familiar with the short form of Materiovigilance programme of India, which then increased to 100% after the session. 96.7 % of nursing professional already aware about the medical device adverse event monitoring centre which then converted to 100% after attending the session by the nursing professionals. Around 61.2% of participants already knew that which is the concern department for reporting of medical device adverse events in our institute, which boost up to 100% after the session. 90.3% of nursing professional prior to the training session answered that reporting of Medical device adverse event for healthcare professionals is mandatory and after the session 96.7% of nursing professionals changed their opinion to voluntary. Regarding Where to report Medical device adverse event, 77.4 % nursing professionals gave the correct response which increased to 96.7 after the session. 61.2 % of nursing professional agreed that the reporting of medical device adverse events to MvPI could not attract legal complications towards them from the regulatory authority and thereby made a contribution towards a meaningful outcome and after attending the session, 90.3% nursing professional gave response correctly. All nursing professionals were already aware that reporting of medical device related adverse events is their professional as well as ethical responsibility, already had the knowledge regarding who all can report the medical device adverse event and knew the benefits of materiovigilance even before the training session. [Table 1] summarizes the responses of participants pre and post training sessions.

4. Discussion

Since years healthcare professionals are using medical devices for the benefit of the patient. Still the idea of reporting of MDAE in India is in its initial phases, and there are only few studies available regarding the awareness of medical professionals of materiovigilance, therefore, the present study was designed to evaluate the impact of awareness cum sensitization programme on healthcare professionals in a tertiary care teaching institute of South Delhi.

The nursing professionals who has participated in this study had limited knowledge towards Materiovigilance. Most of them were not even aware about the MvPI initiated by the Ministry of Health and family Welfare (MoHFW),

Government of India to monitor the MDAE. Likewise, most of them were not having any idea or concept where to report an MDAE. Possibly, it might be due to a reason that unlike pharmacovigilance,[10] materiovigilance has not captured much attention from medical professionals so far. This could be because of lack of awareness and active reporting system. A similar study conducted in Romania also found the similar results.[11] Another study done by Gagliardi et al., which showed that medicals professionals have mentioned various factors like lack of proper reporting system, absence of a conducive environment as some of the obstacles coming in the smooth conduction of materiovigilance.[12]

Non-reporting or underreporting of MDAE are quite prevalent. According to the reports shared by the Food and Drug Administration, only 0.5% of adverse events that are linked with the medical device are reported.[13]

Materiovigilance is a relatively new and small domain. Only few hospitals in India has been enrolled under MvPI.[14] The lack of knowledge regarding materiovigilance is a big concern. Medical devices adverse event cause considerable burden on healthcare system worldwide.[15] To be effective, with the objective of collection of reliable data gathered from regular and vigilant reporting and collecting MDAEs from the motivated healthcare professionals would need an ambitious awareness cum sensitization program. Training session provide the knowledge regarding materiovigilance with the task of motivating their colleagues to report MDAEs to promote the reporting culture.

Thus, we understand that reporting culture among the HCP might get better by measures such as Continuous Medical Education, training programs or workshops. A research study done by Coyle et al. showed that early exposure of postgraduate medical students to the medical education curriculum for reporting of medical event had certainly influence their reporting attitude.[16]

The weakness of the present study was that it has been conducted in only one institute with a small sample size which might not give the correct picture of all HCP across India.

5. Conclusion

From the present study it has been concluded that the knowledge of materiovigilance among health care professionals of our tertiary care teaching institute is inadequate. However, continuous awareness programme among HCP on materiovigilance would be helpful in improving the knowledge and also motivated them to report MDAEs with full enthusiasm. Their positive attitude after the session toward reporting of medical device adverse event is reassuring.

6. Source of Funding

None.

7. Conflicts of Interest

No conflicts of interest.

References

1. Jefferys DB. The regulation of medical devices and the role of the Medical Devices Agency. *Br J Clin Pharmacol*. 2001;52(3):229–35. doi:10.1046/j.0306-5251.2001.01416.x.
2. Maisel WH. Medical device regulation: An introduction for the practicing physician. *Ann Intern Med*. 2004;140(4):296–302. doi:10.7326/0003-4819-140-4-200402170-00012.
3. WHO to Develop Essential Diagnostic List. [Last accessed on 2019 Jul 25].; 2019. Available from: https://www.who.int/medical_devices/en/.
4. Heneghan C, Thompson M, Billingsley M, Cohen D. Medical-device recalls in the UK and the device-regulation process: Retrospective review of safety notices and alerts. *BMJ Open*. 2011;1:e000155. doi:10.1136/bmjopen-2011-000155.
5. Carr AJ, Robertsson O, Graves S, Price AJ, Arden NK, Judge A, et al. Knee replacement. *Lancet*. 2012;379(9823):1331–40. doi:10.1016/S0140-6736(11)60752-6.
6. Curfman GD, Redberg RF. Medical devices - Balancing regulation and innovation. *N Engl J Med*. 2011;365(11):975–7. doi:10.1056/NEJMp1109094.
7. Kumar P, Kalaiselvan V, Kaur I, Thota P, Singh GN. Materiovigilance programme of India (MVPI): A step towards patient safety for medical devices. *Eur J Biomed Pharm Sci*. 2016;12(7):497–501. doi:10.1038/nchembio.2079.
8. Meher BR. Materiovigilance: An Indian perspective. *Perspect Clin Res*. 2018;9(4):175–8.
9. Meher BR, Padhy BM, Srinivasan A, Mohanty RR. Awareness, attitude, and practice of materiovigilance among medical professionals at a tertiary care institute of national importance: A cross-sectional study. *Perspect Clin Res*. 2021;13(2):94–8. doi:10.4103/picr.PICR_187_19.
10. Nabi N, Rehman S, Knowledge SO. Attitude and Practices among Healthcare Professionals Regarding the Adverse Drug Reaction Monitoring and Reporting at a Tertiary Care Teaching Hospital. *Bangladesh J Med Sci*. 2022;21(3):648–58. doi:10.3329/bjms.v21i3.59581.
11. Mirel S, Colobatiu L, Fasniuc E, Boboia A, Gherman C, Mirel V. Materiovigilance and Medical Devices. In: International Conference on Advancements of Medicine and Health Care through Technology; 5th – 7th June 2014. Cluj-Napoca, Romania; 2019. p. 101–6. Available from: https://link.springer.com/chapter/10.1007/978-3-319-07653-9_21.
12. Gagliardi AR, Ducey A, Lehoux P, Turgeon T, Ross S, Trbovich P, et al. Determinants of reporting adverse medical device events: qualitative interviews with physicians about higher-risk implantable devices. *BMJ Qual Saf*. 2018;27(3):190–8. doi:10.1136/bmjqs-2017-006481.
13. Teow N, Siegel SJ. FDA regulation of medical devices and medical device reporting. *Pharmaceut Reg Affairs*. 2013;2(2):110. doi:10.4172/2167-7689.1000110.
14. Available from: https://medicaldialogues.in/pdf_upload/e-newsletterapril2021issue-2-154988.pdf.
15. Hefflin BJ, Gross TP, Schroeder TJ. Estimates of medical device–associated adverse events from emergency departments. *Am J Prev Med*. 2004;27(3):246–53. doi:10.1016/j.amepre.2004.04.005.
16. Coyle YM, Mercer SQ, Murphy-Cullen CL, Schneider GW, Hynan LS. Effectiveness of a graduate medical education program for improving medical event reporting attitude and behavior. *Qual Saf Health Care*. 2005;14(5):383–8. doi:10.1136/qshc.2005.013979.

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Cite this article: Rehman S, Ray A, Pandit S. Materiovigilance: Impact of awareness cum sensitization programme on healthcare professionals of a tertiary care teaching hospital in South Delhi. *IP Int J Comprehensive Adv Pharmacol* 2022;7(3):146-150.