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Knowledge, Attitude and Practices of Materiovigilance among the Medical Students and Non-Medical People: A Cross-Sectional Study

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ABSTRACT: Background: Post-market surveillance plays a pivotal role in ensuring the quality, safety, and efficacy of medical devices, given the potential serious implications of adverse events associated with these devices. Raising awareness about materiovigilance and Medical Device-Associated Adverse Events (MDAEs) among the general population is a fundamental step in this direction. Materiovigilance programme of India (MvPI) to monitor the safety of medical devices in the country has been approved for the commencement by the Ministry of health & family welfare, Govt. of India. The MvPI was formally launched on 06th July 2015 at IPC, Ghaziabad by DCGI. **Aim and Objective:** To determine the knowledge of materiovigilance among the people and spreading awareness of materiovigilance among mainly non-medical community. **Materials and Methods:** This was a cross-sectional questionnaire-based survey done among medical students and non-medical people. A self-administered, pre-tested, structured, pre-validated questionnaire was distributed to 400 people. The questionnaire consists of 6 questions pertaining to knowledge of materiovigilance. A survey software "google form" was used to analyze the data. **Results:** A total of 312 responses were received. 88 people were not willing to participate in the study so they were excluded. Only 3 % (13) of the community had complete knowledge about various aspects of materiovigilance and MvPI. About 9% (35) of people had adequate knowledge. 21% (82) of community had moderate knowledge. About 21.34% (84) people only knew about medical devices. 24% (98) were even did not know what are medical devices.

KEYWORDS: Medical Devices; Medical Device-Associated Adverse Events; Materiovigilance; Materiovigilance Programme of India.

I. INTRODUCTION :

Post-market surveillance plays a pivotal role in ensuring the quality, safety, and efficacy of medical devices, given the potential serious implications of adverse events associated with these devices[1]. 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[2]. Moreover, it has even resulted in significant morbidity and mortality among device users or beneficiaries. Several pieces of technology, including pacemakers, MRI machines, breast implants, and incubators, have been recalled owing to malfunction[3].

Medical devices can be classified in the following manner (The Central Drugs Standard Control Organisation [CDSCO], Medical Devices Rules 2017/MHRA or GHTF)[4,5,6].

- Class a: Low risk (alcohol swabs, absorbent cotton wools, and surgical dressing)
- Class b: Low moderate risk (B.P. monitoring device, thermometer, disinfectants, etc.)
- Class c: Moderate high risk (hemodialysis, implants, and catheter)
- Class d: High risk (Cochlear implant and pace-making devices).

On July 6, 2015, the Indian Drugs Controller General unveiled the Materiovigilance Programme of India (MvPI) at the IPC in Ghaziabad. The main goals of this program are to track adverse events related to medical devices (MDAE), raise awareness among health-care professionals about the value of MDAE reporting, and produce and disseminate independent, trustworthy, and evidence-based safety data for medical devices. The CDSCO regulates MvPI, while the IPC serves as the national coordination center[4,7].

A systematic programmatic method has

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been used to recognize medical colleges, hospitals, and other institutions as medical device adverse event monitoring centers (MDMCs) across the nation to enable adverse event reporting from a region[6]. The MDMCs are primarily in charge of keeping track of and informing MvPI of any adverse occurrences that occur inside their institution. A clinician, pharmacologist, biomedical engineer, or other health-care professionals are given these duties by the concerned center as coordinator or deputy coordinator. The MDMCs are also in charge of educating the public and advocating for MvPI and developing a culture of reporting adverse events[8].

The MvPI aims at:
1. Establishing a national strategy for assessing patient safety
2. Analysing the medical device's benefit–risk ratio
3. Producing evidence-based data regarding medical equipment linked to unfavourable outcomes
4. Assisting the CDSCO in making decisions about medical device regulation in the nation
5. Exchanging safety-based information with different industry stakeholders
6. Working with other health-care organizations and international organizations to exchange information and manage data[9].

The current study was carried out with the objective to determine the knowledge of materiovigilance among the people and spreading awareness of materiovigilance among mainly non-medical community.

II. MATERIALS AND METHODS

This survey was conducted using a cross-sectional questionnaire among medical students and non-medical people. A self-administered, pre-tested, structured, pre-validated questionnaire was distributed to 400 people. The survey comprises of 6 inquiries about knowledge of materiovigilance. A survey software "google form" was used to analyze the data.

EXCLUSION CRITERIA

All students and other people were not willing to participate in the study. The participants who fulfilled the inclusion and exclusion criteria were included in the study. Details and purpose of the study were explained to the medical students as well as non-medical people and informed consent for the participation in the study was taken through Google forms and questionnaire was sent to the participant through Google form through Email or WhatsApp. The questionnaire consisted of 6 questions.

The study variables were summarized by routine descriptive statistics. Data were entered into a Microsoft Excel spreadsheet and, then, analyzed.

III. RESULTS

The survey questionnaire was sent to all 400 people who are studying in medical colleges and some local people, among them 312 responded completely. 88 people were not willing to take part in the research so they were excluded. There were 247 medical students, 65 were non-medical people. The average response rate was 78%. In our study, female participants were 188 (77.4%) and 55 (22.6%) were males. Out of 243 participants.

Only 3 % (13) of the community had complete understanding of numerous elements of MvPI and materiovigilance. About 9% (35) of people had adequate knowledge. 21% (82) of community had moderate knowledge. About 21.34% (84) people only knew about medical devices. 24% (98) were even did not know what are medical devices.

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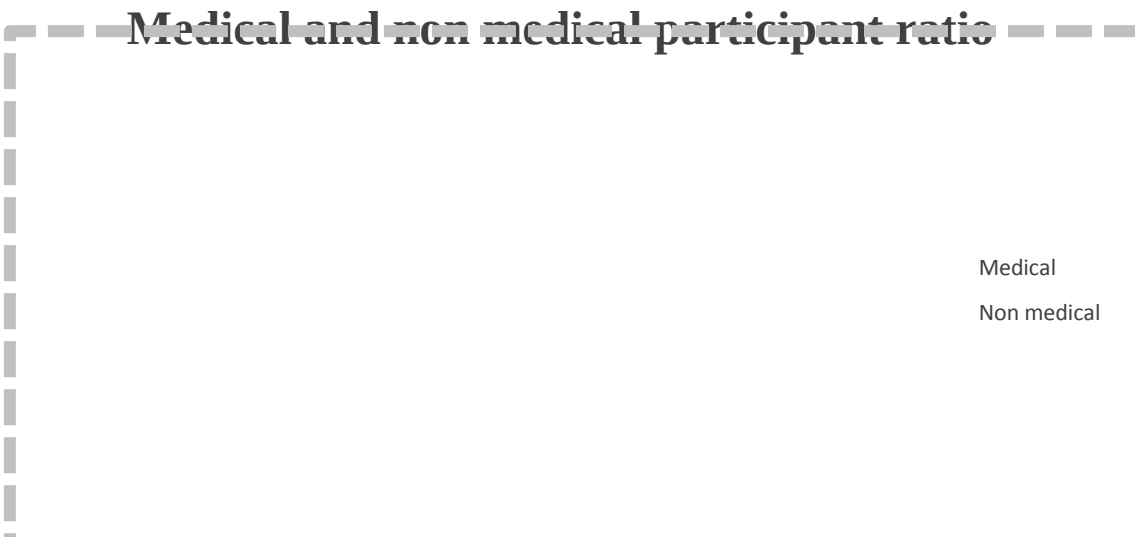

FIG. 1: Medical and non-medical participants ratio

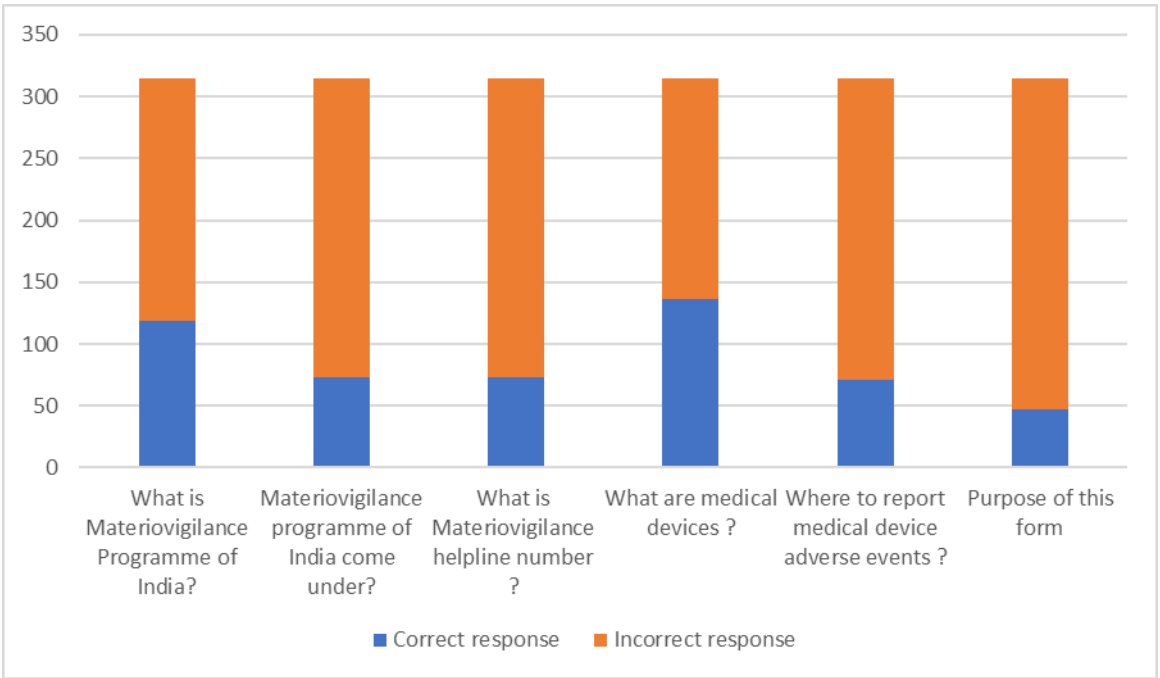

FIG. 2: Correct responses and incorrect responses

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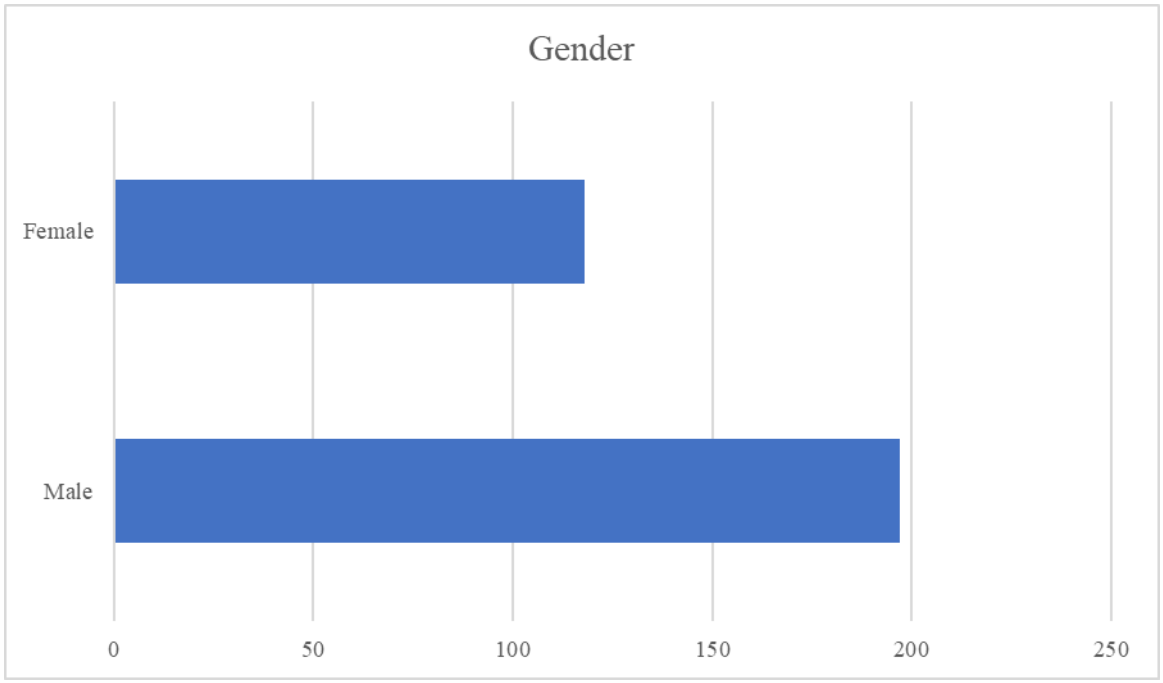

FIG. 3: Gender ratio

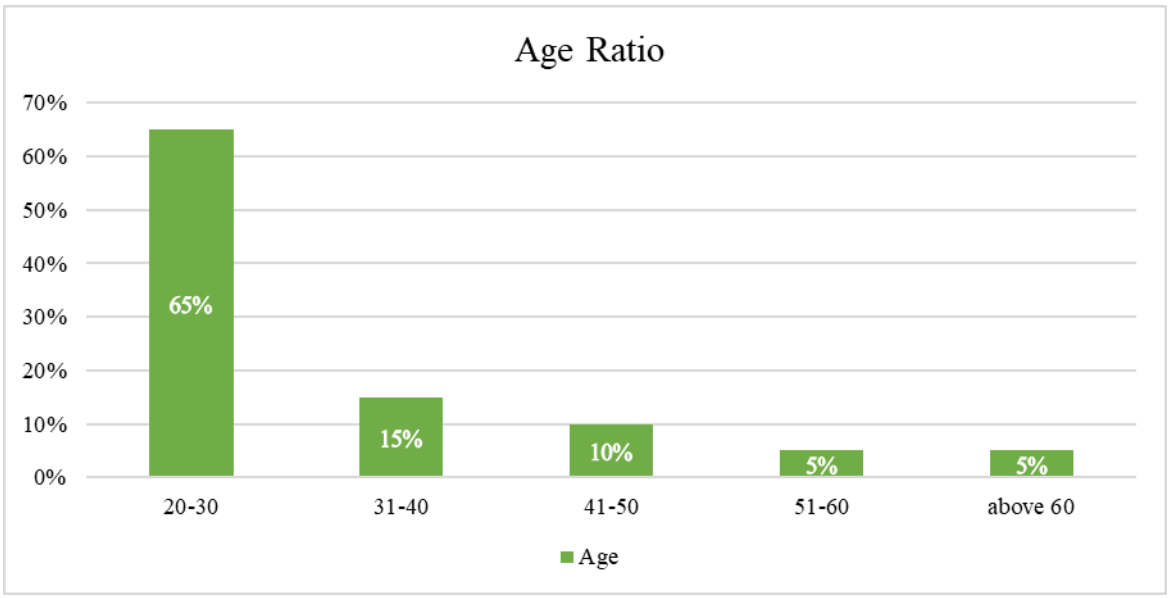

FIG. 4: Age wise distribution

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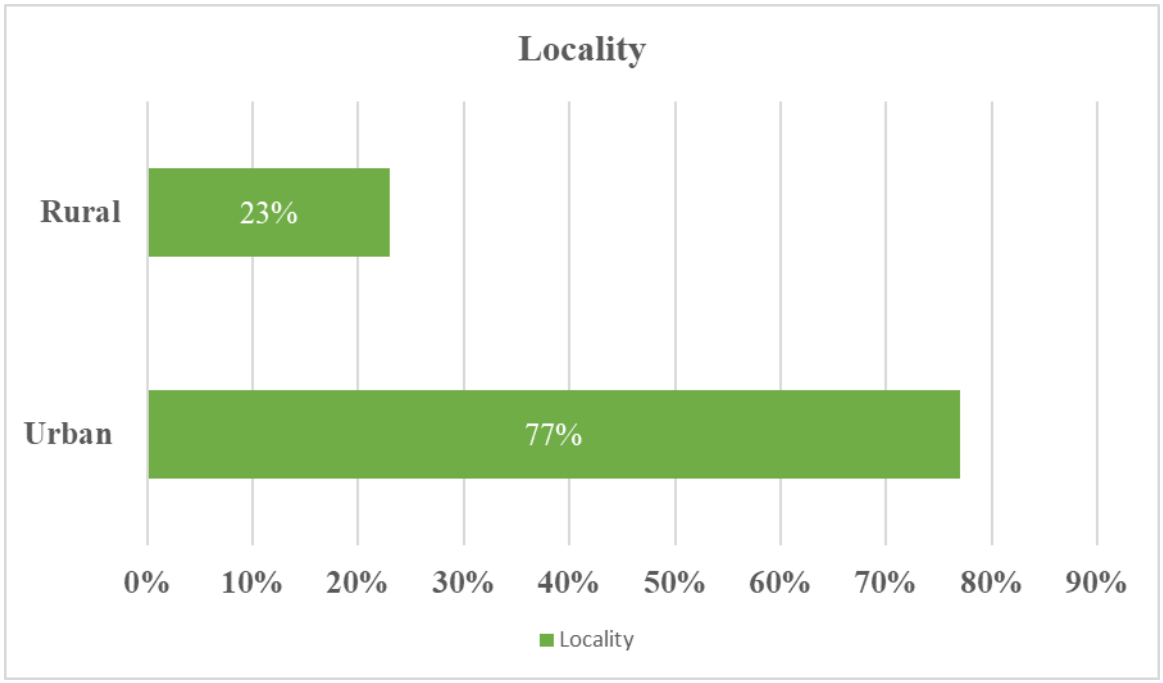

FIG. 5: Place of residence (urban and rural)

IV. DISCUSSION

For many years, medical devices have been utilized in patient treatment. Nevertheless, the idea of MDAE reporting is still relatively new in India, and very little information concerning medical professionals' attitudes and levels of understanding of materiovigilance is publicly available[10].

Participants in this study who were medical professionals knew very little about Materiovigilance. Many of them were unaware of the present MvPI, which is being monitored by the Indian government as part of MDAE. Like this, a lot of them were clueless on where to file a report for MDAE. Maybe this is because, in contrast to pharmacovigilance, materiovigilance has not yet captivated the public's attention[11].

MDAE underreporting is pervasive across the globe. The Food and Drug Administration claims that only 0.5 percent of the device's adverse occurrences are recorded[2]. Participants in this study demonstrated a favorable attitude about MDAE despite their lack of understanding. Most of them believed that adverse events from medical devices may occur and that reporting those events would improve patient safety[13,14].

The individuals in our study have very poor practices when it comes to reporting adverse events. This can be the result of inadequate reporting procedures and awareness.

V. CONCLUSION

Among the studied participants, there was a lack of knowledge and awareness about the Materiovigilance Programme of India, only 3-5% of medical students were aware of MvPI. To enhance spontaneous reporting of MDAEs, create awareness among whole community through monthly conferences, through pasting poster on walls, through workshops and academic activities for medical students.

CONFLICT OF INTEREST:

The authors have no conflicts of interest regarding this investigation**.**

REFERENCES:

[1]. Maisel WH. Medical device regulation: An introduction for the practicing physician. Ann Intern Med. 2004;140: 296–302.
[2]. Jefferys DB. The regulation of medical devices and the role of the Medical Devices Agency. Br J Clin Pharmacol 2001;52: 229-35.
[3]. Gupta P, Janodia MD, Jagadish PC, Udupa N. Medical device vigilance

systems: India, US, UK, and Australia. Med Devices (Auckl) 2010;3: 67-79.

[4]. Manna N, Mazumdar SD, Panchanan P, Das S. A study of assessing knowledge, attitude, and practice of Materiovigilance among staff nurses in Medical College and Hospital, Kolkata. Natl J Physiol Pharm Pharmacol 2023;13(07):1584-1590.

[5]. Mirel S, Colobatiu L, Fasniuc E, Boboia A, Gherman C, Mirel V, et al. Materiovigilance and medical devices. In: Vlad S, Ciupa R, editors. International Conference on Advancements of Medicine and Health Care through Technology, Cluj-Napoca, Romania. IFMBE Proceedings. Vol. 44. Cham: Springer; 2014.

[6]. 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 2022;13: 94-8.

[7]. Meher BR. Materiovigilance: An Indian perspective. Perspect Clin Res 2018;9: 175-8.

[8]. 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: 497-501.

[9]. Radhadevi N, Balamuralidhara V, Kumar TP, Ravi V. Regulatory guidelines for medical devices in India: An overview. Asian J Pharm 2012;6: 10-7.

[10]. Guidance Document, Materiovigilance Programme of India (MvPI). Available from: file:///D:/New%20folder%20(8)/mate riovigilance/ materiovigilance%20programme%20of%20india.pdf. [Last accessed on 2019 Jul 17].

[11]. Mirel S. Knowledge about Materiovigilance in Cluj-Napoca, Romania. Available from: http://origin.who.int/medical_devices/global_ forum/3rd_gfmd/3rd_gf_Post ers/en/index 14.html. [Last accessed on 2019 Aug 16].

[12]. Teow N, Siegel SJ. FDA regulation of medical devices and medical device reporting. Pharmaceut Reg Affairs 2013;2: 110.

[13]. Kurien S, Satapathy S, Gupta SK, Arya SK, Sharma DK. Study of reporting system for adverse events related to common medical devices at a tertiary care public sector hospital in India. World Acad Sci Eng Technol Int J Health Med Eng 2014;8: 448-53

[14]. 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: 190-8.