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Assessment of Consumer Awareness on Medical Device Adverse Events in A Community Centered Study

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Abstract
Materiovigilance is the study and follow up of incidents that might result from the use of medical devices. All the Medical devices may have certain degree of risk and can cause some problems under specific circumstances. A cross-sectional prospective study was conducted to assess and evaluate the knowledge, Attitude and Practice of materiovigilance among consumers. This study was carried out for a period of six months at a tertiary care teaching hospital and community with a sample size of 150 consumers. Data was collected from consumer in hospital and community. Data was collected and analyzed using descriptive statistics like total numbers, percentage and mean. Microsoft words and Excel have been used to generate graphs and tables. A total of 150 samples were collected, from the consumers who visited NMCH & RC, Raichur and the community visit. Most of the consumers 83 (55.3%) were aged 18 -28 years. Male were more 99(66%) and females were only 51(34%). Majority of consumers that is 56(37.3%) were Students. Out of 150 consumers, about 127(84.6%) consumers don't know what is materiovigilance and only 33(22%) known on materiovigilance. Only 63(43.3%) consumers believe there is a need for more public education and awareness campaigns about MV and about 87(58%) consumers have not various educational interventions and proper training are necessary to promote the reporting of medical device induced adverse events. It is found that majority of consumers don't have knowledge on medical devices and adverse events associated with it and were unaware of the term materiovigilance. Positive attitude was noted but reporting practices and awareness of MDAEs were very less. Therefore, there is a need to increase consumers awareness in medical device adverse event reporting.

Keywords: Adverse Events, Consumers, Materiovigilance, Medical Device Adverse Events.

INTRODUCTION

The World Health Organization defines a medical device as any instrument, implement, machine, apparatus, material, reagent for in vitro use, software, or other related article intended by the manufacturer to be used, alone or in combination for prevention, diagnosis, treatment, or alleviation of disease or injury.

Medical device ranges from simple surgical hand gloves or syringes to infusion pumps and artificial pacemakers, as well as complex diagnostic devices such as MRI (Magnetic resonance imaging) machines. Medical devices are now widely employed in all areas of surgical, medical, and community health care. Medical devices have played the utmost important role in patient care.[1]

Materiovigilance is the coordinated system of identification, collection, reporting, and analysis of untoward events associated with the use of medical devices (MDs) and protection of patient's health by preventing its occurrences. Today, we are using more than 1 million MDs available ranging from simple bandage/tongue depressor to the complex devices such as magnetic resonance imaging MD not only provide immense benefits to the patients, they have also extended the ability of clinicians to diagnose and treat various diseases.[2]

The basic goal of materiovigilance program is to create awareness about the significance of reporting of adverse events caused by medical devices, to monitor adverse events and collect independent credible evidence-based safety data of medical devices and to share it among health providers across the nation. Hence, there is an utmost need of health-care professionals to learn about it, to ensure wellbeing of patient and prevent injuries and complications. Only limited number of studies were carried out regarding awareness of materiovigilance.[3]

To monitor the safety of the use of medical devices in the country, the Ministry of Health & Family Welfare, Govt of India, approved and commenced the materiovigilance Programme of India (MvPI) in the country. The MvPI launched on 6th July 2015 at the Indian Pharmacopoeia Commission, Ghaziabad by the Drugs Controller General of India (DCG(I). Indian Pharmacopoeia Commission (IPC) is an autonomous institution under the Ministry of Health & Family Welfare and also functions as the National Coordination Centre for the Materiovigilance Programme of India. Sree Chitra Tirunal Institute of Medical Sciences & Technology (SCTIMST), Thiruvananthapuram, will function as a National Collaborating Centre for MvPI.[4]

The MvPI aims to systematically monitor MDAEs, generate evidence-based safety data, and raise awareness among healthcare professionals and the public. From its inception to October 2019, the program reported 1,931 adverse events, with 66.12% classified as serious. Cardiac stents accounted for 47.95% of the reported events, followed by intrauterine contraceptive devices and orthopaedic implants.[5]

Consumer awareness of materiovigilance concerning medical devices is crucial for ensuring patient safety and promoting informed decision-making. By understanding the importance of materiovigilance, individuals can actively participate in reporting adverse events or device malfunctions they encounter. This proactive engagement facilitates the early detection and mitigation of potential risks associated with medical devices, ultimately enhancing patient safety and well-being. Moreover, consumer awareness empowers individuals to make informed choices regarding their healthcare, as they can weigh the benefits and risks of different devices based on reliable information. This collaborative approach between consumers, healthcare professionals, regulatory agencies, and manufacturers fosters a transparent environment where product safety and quality are prioritized, thereby contributing to the overall improvement of healthcare standards.[6]

Objectives

Consumers, as end users of medical devices, play a crucial role in the success of materiovigilance programs. However, there is limited awareness and reporting of adverse events among consumers. To

address this, the study titled "Assessment of Consumer Awareness on Medical Devices Adverse Events Community-Cantered Study" was conducted with the following objectives:

- To assess consumer knowledge, attitudes, and practices regarding medical devices and materiovigilance.
- To explore factors contributing to the underreporting of MDAEs by consumers (MvPI) among the public.
- To create awareness on medical device adverse events (MDAES) and Materiovigilance program of India (MvPI) to public.

By empowering consumers with knowledge and encouraging active participation in reporting, this study aims to strengthen the materiovigilance framework, ensuring improved safety, better regulatory decisions, and enhanced public health outcomes.

Review of Literature

Several studies highlight a significant gap in consumer awareness regarding medical device adverse events (MDAEs) and the reporting mechanisms in place. Panchal YN et al., (2023) found that while most healthcare professionals were aware of reporting systems, few knew about the national monitoring program, and even fewer had reported adverse events, suggesting a need for increased training and awareness. Similarly, Rehman S et al., (2023) demonstrated that targeted educational interventions among nursing professionals significantly raised awareness of materiovigilance. Tantia R et al., (2023) noted that while many professionals recognized the potential risks of medical devices, only a small percentage knew how to report these risks, indicating a need for clearer communication on reporting channels. Manna N et al., (2023) found a high rate of under reporting of MDAEs, even when identified, highlighting the necessity of robust consumer education programs to improve awareness and reporting behavior. These studies underscore the importance of community center educational initiatives to enhance consumer knowledge and safety regarding MDAEs.

Methodology

The study was carried out from February 2024 to August 2024 in Navodaya Medical College Hospital & Research Center, Raichur.

Study design: Questionnaire based cross – sectional study.
Study Site: Navodaya Medical College, Hospital & Research Centre, Raichur.
Sample Size: 150 consumers.
Study period: 6 months (February 2024 to August 2024).
Data Collection: Data will be collected using questionnaire.

Inclusion Criteria:

- The study population are the consumers who were used or currently using of the medical device.
- Individuals with different levels of experience on usage of medical devices.

Exclusion Criteria:

- The consumer who are not willing to give consent /participate in the study.
- Participants with limited or no exposure to medical devices and materials.

Results and Discussion

The study assessed consumer awareness of medical device adverse events and materiovigilance among 150 participants using a pre designed questionnaire form to assess and evaluate the knowledge attitude practice among consumers in a tertiary care hospital and community. Key findings are summarized.

Table 1: Age Distribution of Study Participants (n=150)

Age (Year)	No. of Participants	Percentage (%)
18-28	83	55.3
29-38	30	20
39-48	19	12.66
49-58	18	12
Mean Age		31.63

According to the data, most of the respondents 83(55.3%) were aged 18 -28 years, followed by 29 -38 years 30(20%), 39-48 years were 19(13%) and least number of consumers were from the age group 49-58 years, were 18(12%) respectively. It is assessed knowledge, attitude and practices of consumers on materiovigilance and medical device adverse event.

Table 2: Gender Distribution of Study Participants (n=150)

Gender	Number of Participants	Percentage (%)
Male	99	66
Female	51	34
Total	150	100

Respondents gender distribution, male were more 99(66%) and females were only 51(34%). It is assessed KAP of consumers on Materiovigilance and medical device adverse event.

Table 3: Occupational Status of Study Participants (n=150)

Occupation	Number of Participants	Percentage (%)
Labour	15	10
Housewife	30	20
Others	49	32.6
Students	56	37.3

The data table showed that out of 150 consumers, 56(37.3%) consumers were Students, 49(33%) consumers were from others different occupation,30(20%) consumers were housewives and 15(10%) were Labour. It is assessed knowledge, attitude and practices of consumers on materiovigilance and medical device adverse event is assessed.

Table 4: Assessment of Knowledge on Medical Device Adverse Event (MDAE) and Materiovigilance Among Consumers (n= 150)

SL. No	Questions	Number	Percentage (%)
1	Do you know what is Materiovigilance?		

	Yes	33	22
	No	127	84.6
2	Do you know that medical devices can cause adverse events?		
	Yes	84	56
	No	66	44
3	Are you aware about the Materiovigilance programme of India to monitor adverse events due to medical devices?		
	Yes	114	76
	No	36	24
4	Do you know where is the National Collaborating Centre of Materiovigilance programme of India located?		
	Ghaziabad, Delhi	30	20
	Bengaluru, Karnataka	29	19.3
	Hyderabad, Telangana	22	14.6
	Don't know	69	46
5	Who all can report adverse events due to medical devices?		
	Physician	27	18
	Pharmacist	34	22.6
	Nurse	7	4.66
	All of the above	82	54.66

As show in table 4 that out of 150 consumers, about 127(84.6%) consumers don't know what is materiovigilance and only 33(22%) consumers known. About 84(56%) consumers don't know whether medical device can cause adverse events and only 66(44%) consumers known. We found that 114(76%) consumers did not aware about MvPI to monitor medical devices adverse events and only 36(24%) consumers were aware. When asked where is National Collaborating Center of MvPI located, almost 69 (46%) don't know where it was, were 30 (20%) consumers saying in Ghaziabad, Delhi, were 29(19.3%) consumers say in Bangalore, Karnataka and 22(14.6%) consumers say in Hyderabad, Telangana. When asked who can report adverse events due to medical devices out of 150 consumers, about 82(55%) consumers choose all of the above, were 27(18%) consumers choose Physician, were 34(22%) consumers choose Pharmacist, were only 7(5%) consumers choose Nurses. In this study more than half of the participants heard the term materiovigilance for the first time during the conduct of this study the correct definition was not known to consumers. This is one of the key findings in this study. According to previous studies, consumers who participate in this study having limited knowledge regarding the various aspects of materiovigilance and MvPI started in India.

Table 5: Assessment of Attitude on Medical Device Adverse Event and Materiovigilance Among Consumers (n= 150)

S.L No	Questions	Number	Percentage (%)
1	Do you think medical devices can cause adverse events?		

	Yes	69	46
	No	85	57
2	Is Reporting medical device adverse events (MDAE) is a part of duty of healthcare professionals?		
	Yes	65	43.3
	No	85	54
3	Do you think reporting of any adverse events associated with medical device is necessary?		
	Yes	64	42.6
	No	86	57.3
4	Do you think reporting of adverse event due to medical devices will enhance patient safety?		
	Yes	60	40
	No	90	60
5	Do you think only persistent disabilities should be reported?		
	Yes	50	33.33
	No	100	66.66
6	Which of the following can report adverse events due to medical device used?		
	Physician	30	60
	Pharmacist	28	18.9
	Nurse	7	5
	All of the above	85	56.6

As show in table 5 that out of 150 consumers, only 69(46%) consumers think that medical devices can cause adverse events in patients and 85(57%) consumers do not feel as that. About 65(43.3%) said reporting medical device adverse event (MDAE) is a part of healthcare professionals and 85(57%) consumers felt that reporting medical device adverse event (MDAE) is not a part of healthcare professionals. Only 69(46%) consumers think that medical devices can cause adverse, were about 81(54%) consumers didn't think so. Only 65(43.3%) consumers think that reporting medical device adverse events is a part of duty of healthcare professional, were about 85(57%) consumers didn't think so. Out of 150 consumers**,** when asked whom can report adverse events due to medical devices, about 85(57%) consumers choose all of the above, were 30(60%) consumers choose Physician, were 28(19%) consumers choose Pharmacist, were only 7(5%) consumers choose Nurses. Only 64(43%) consumers think that reporting of adverse event with medical device is necessary and majority 86(57.3%) consumers think reporting are not necessary. Only 60(40%) consumers think reporting of adverse event due to medical devices will enhance patient safety and about 90(60%) consumers did not think so. Only 50(33.33%) consumers think only persistent disabilities need to be reported and about 100(67%) consumers did not think as such. In our study most the consumers opined that reporting medical device adverse event is a part of healthcare professionals and it will enhance the patient safety. Although there was less awareness among consumers comparatively. It is assessed the practice on medical device adverse event and materiovigilance among consumers.

Table 6: Assessment of Practice on Medical Device Adverse Event and Materiovigilance Among Consumers (n= 150)

SL. No	Questions	Number	Percentage (%)
1	Do you actively seek information about the safety and performance of medical devices before using them?		
	Yes	66	44
	No	84	56
2	Do you believe there is a need for more public education and awareness campaigns about materiovigilance and medical device safety?		
	Yes	63	43.3
	No	87	58
3	Do you ever search information about medical device before using them?		
	Yes	62	41.3
	No	88	58.66
4	Are you aware of any adverse events or device malfunctions that have been reported in connection with the medical device you have used?		
	Yes	59	39.3
	No	91	60.6

It was found that out of 150 consumers, only 66(44%) consumers have actively sought information and performance of medical device before using, about 84(56%) consumers did not. Only 63(43.3%) consumers believe there is a need for more public education and awareness campaigns about materiovigilance and on safety of medical devices and about 87(58%) consumers have not believed on materiovigilance safety of medical devices. Out of 150 consumers, only 62(41.3%) consumers have search information about MD before using them, about 88(59%) consumers have not searching information about MD before using them. Only 59(39.3%) consumers have been aware about MD adverse events or device malfunctions before using them and about 91(61%) consumers have not been aware about MD adverse events or device malfunctions before using them. The practice of adverse event reporting among the participants in this study was extremely poor. Many of them neither searching information nor seek information related to medical device adverse event or reported any adverse events. This could be due to lack of awareness and improper reporting system.

Conclusion

Consumers were not aware of reporting systems and others were confused about reporting. We found that, the knowledge, attitude, practice and awareness of medical devices adverse events and materiovigilance were inadequate. Various educational interventions and proper hands-on training are necessary to promote the reporting of medical device induced adverse events. Furthermore, a special emphasis on materiovigilance in the community (consumers) is required to raise awareness about the rational usage of medical devices.

Ethics Followed

- Participant information, questionnaire and consent form in English, Hindi and Kannada. Participant

information Name, gender, age and occupation. Participant consent includes the Name, gender and Age. It also included the patients Written consent for participating in our study along with his/her signature. Questionnaires consisted of four sections (A, B, C, D).

- Obtaining Consent from the Hospital Authority. It is a custom that every project work carried out in the hospital by the department of Pharmacy Practice has to be approved by the Medical Superintendent, and same should be informed to all the physicians and surgeons of the hospital. For obtaining the consent a study protocol was prepared, which includes the proposed title, study site, duration, inclusion and exclusion criteria, objectives and a brief methodology about the work to be carried out. Then the protocol of the study was submitted to the Medical Superintendent of the hospital.
- The study wards were visited daily as per schedule and on the community. A total of 150 cases were collected from a consumer s which is in General medicine, OBG, Orthopedic, Surgery ward and also from the community. Approached participants and explained about the study purpose.
- Data from the questionnaire were analyzed using descriptive statistics namely total numbers, percentage and mean. Microsoft word and excel have been used to generate graphs, table.

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2. Dr. H Doddayya, M. Pharm, Phd, Principal and Professor, NET Pharmacy College, Raichur-584103, Karnataka, India. With expertise in healthcare education, provided valuable support and guidance for the study on consumer awareness of medical device use.
3. Banshanlang Ymbon, Pharm.D Intern, Department of Pharmacy Practice, NET Pharmacy College, Raichur584103, Karnataka, India. Research focuses on consumer awareness of medical device usage, and he is actively collecting data to assess knowledge levels and identify gaps in understanding. His work aims to support better health education and safer medical practices.
4. Dr. Muhsin R, Pharm.D, Lecturer, Department of Pharmacy Practice, NET Pharmacy College, Raichur584103, Karnataka, India. Contributions were crucial in shaping the direction of the study and enhancing its focus on consumer awareness and the safe use of medical devices.

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