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Impact of Educational Intervention on Knowledge, Attitude and Practice of Materiovigilance among Healthcare Professionals: A Hospital Centered Study

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Abstract

Background: The medical devices sector in India plays a crucial role in the country's healthcare system, ranging from simple bandages to complex devices like CT scans. Materiovigilance is a system for monitoring adverse events related to medical devices. The program empowers healthcare professionals to report adverse events, ensuring patient safety and improving the overall quality of healthcare through systematic surveillance and data analysis. ***Objective:*** To assess knowledge, attitude and practice of healthcare professionals toward materiovigilance and evaluate the impact of an educational intervention on these aspects. ***Methods:*** A cross-sectional prospective questionnaire study was conducted for a period of six months at a tertiary care teaching hospital with a sample size of 307 healthcare professionals. Healthcare professionals from Medical, Nursing, Pharmacy, Dental and Physiotherapy were included in the study. Base line data was collected by administering questionnaire. Educational intervention was provided to the same study participants and post interventional data was also collected. Chi-square test was used to test the significance of impact of educational intervention. ***Results:*** The collected data showed that 94.46% (290) were under the age group of 18-28. Before the intervention, only 36.16% (141) were aware of the term materiovigilance which increased to 100% (307) after the intervention. Before the intervention, 65.47% (201) did not know where the NCC of MvPi is located and 16.94% (52) gave the wrong answer, whereas after the intervention 88.6% (272) participants gave the right answer. ***Conclusion:*** Our study identified a significant knowledge gap in materiovigilance among healthcare professionals before the educational intervention. After the intervention, participants demonstrated a substantial increase in their knowledge and awareness of medical device-related adverse events (MDAEs).

Keywords: Adverse events, Educational intervention, Healthcare professionals, Materiovigilance, Medical devices.

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 [1-4]. Medical devices have played the utmost important role in patient care [2]. Despite the fact that medical devices provide benefit to the patients, its use is not completely devoid of risk. It can cause morbidity and mortality in the patients or users of medical device [3,6].

Materiovigilance (MV) is the coordinated system of identification, collection, reporting, and analysis of any untoward events associated with the use of medical devices (MDs) and protection of patient's health by preventing its occurrences. [1-2]. Unlike drugs, the malfunctioning of a single medical device may lead to a community disaster. For example, if a blood pressure monitoring apparatus does not work properly at a community clinic, it might lead to the unwanted prescription of medication to all OPD attending patients [5].

In order to monitor the safety on the use of medical devices in the country, Ministry of Health &

Family Welfare, Govt. of India approved and commenced Materiovigilance Programme of India (MvPI) in the country [3,7]. The programme aims to monitor medical device associated adverse events (MDAEs) and create awareness among healthcare professionals about the importance of MDAEs reporting in India and monitoring the benefit risk profile of the medical devices. Medical Device Adverse Event Monitoring Centers has been identified in order to monitor the safety of medical devices across the country. There is an utmost need of health-care professionals to learn about it, to ensure wellbeing of patient and prevent injuries and complications. [4]

Despite the launch of the Materiovigilance Programme of India, awareness and active participation in MDAE reporting among healthcare professionals remain limited. [3].

The true public health burden of adverse events associated with medical devices is unknown. Even medical students are more vulnerable for serious infections due to chance of direct contact with infected injections and surgical instruments. Many factors may have contributed to these incidents such as manufacturing defects, mishandling, transportation errors, warehouse defects, factors associated with instruction manuals, patient's medical history, and external factors (workload, multitasking, availability of equipment, etc.). Hence, it is necessary to know the health care professionals' knowledge, attitude, and practice towards materiovigilance.[8]

In this backdrop, the study was planned with the objective to provide educational intervention on materiovigilance to healthcare professionals in the study hospital and to evaluate the impact of educational intervention on knowledge, attitude and practice of healthcare professionals regarding materiovigilance.

MATERIALS AND METHODS

Study design: Questionnaire based cross-sectional study.

Study Site: Navodaya Medical College, Hospital & Research Centre, Raichur.

Sample Size: 307 healthcare professionals.

Sampling: Simple random sampling.

Study Period: 6 months (February 2024 to August 2024).

Data Collection: Data was collected using validated questionnaire.

Inclusion Criteria:

- Healthcare professionals who are actively involved in patient care.
- Professionals from various medical specialties.

Exclusion Criteria:

- Healthcare professionals who were not willing to give consent/ participate in the study.
- Non-healthcare professionals or individuals not involved in patient care.
- Participants with limited or no exposure to medical devices and materials.

Designing of Participant Consent Form

Participant Consent form which includes the name, age, gender and designation of the participant and also the written consent for participating in our study along with his/her signature and contact number was prepared.

Designing and validation of Questionnaire

A questionnaire was prepared in English language consisting of questions to assess knowledge, attitude and practice of materiovigilance among healthcare professionals. The questionnaire's internal consistency was adequate, as evidenced by its Cronbach's alpha score of 0.73.

Ethical Considerations

Ethical approval was obtained from the institutional review board.

Questionnaire Distribution, Collection and Analysis of Data

The Project team approached the study participants and discussed about the purpose of the study. Participant consent form was taken from healthcare professionals. An awareness seminar on "Materiovigilance and Reporting of Medical Device Adverse Events" was organized for healthcare professionals (Medical, Dental, Nursing, Pharmacy and Physiotherapy). The method employed were Microsoft Power point presentation in English language. The duration of power point presentation was 15 minutes. The questionnaire was distributed and the healthcare professionals were requested to fill the questionnaire and return them within 10 minutes before seminar. After the seminar, questionnaires were re-administered to the study participants who participated in pre-intervention phase and reassessed the knowledge, attitude, and practice of materiovigilance among healthcare professionals. The data were further analyzed by comparing pre-interventional result with post-interventional result using Chi-square test. Statistical calculations were done by using Statistical Package for Social Science (SPSS) version 20.0.

RESULTS

Table 1 shows socio-demographics of participants which represents age, gender, profession of the participants. Out of 307 participants, most of the respondents 290 (94.46%) were of the age group 18-28

and the remaining participants 17 (5.5%) were of the age group 29-38. The mean age of the study participants is 24.05. Majority of the participants 159 (51.79%) were female and 148 (48.21%) were male. When taking profession into consideration, 92 (33.22%) were Physiotherapists, 62 (20.19%) were Pharmacists, 53 (17.26%) were Nurses, 50 (16.28) were Medical and 50 (16.28) were Dentists.

Table 1: Socio-Demographic Characteristics of Healthcare Professionals (n=307)

S. No	Characteristics	Number (%)
1	**Age group in years**	
	18-28	290 (94.46)
	29-38	17 (5.54)
2	**Gender**	
	Male	148 (48.21)
	Female	159 (51.79)
3	**Profession**	
	Medical	50 (16.28)
	Dental	50 (16.28)
	Nursing	53 (17.26)
	Physiotherapy	92 (29.96)
	Pharmacy	62 (20.19)

Table 2 represents the comparison of knowledge, attitude and practice of study participants before and after the intervention. Before the intervention, only 36.16% (141) were aware of the term materiovigilance which increased to 100% (307) after the intervention, there is an increment of 63.84% which gives a chi square value of 287.904 and p value 0.000 < 0.001.

Around 33% increment was seen on the opinion of who all can report adverse events related to medical devices which gives a chi square value of 86.61 and p value of 0.000 < 0.001. On comparing study participants attitude whether they think medical devices can cause adverse events in patients there was a positive increment of 18% after the intervention which gives a chi square value of 52.048 and p value of 0.000 < 0.001.

Table 2: Comparison of assessment of knowledge, attitude and practice on materiovigilance among healthcare professionals before and after the educational intervention

S. No	Questions	Pre intervention test			Post intervention test			Chi square (χ^2)	P Value
		Yes no.(%)	No no.(%)	Don't know no.(%)	Yes no.(%)	No no.(%)	Don't know no.(%)		
1	Do you know what is materiovigilance?	111 (36.16)	196 (63.84)	-	307 (100)	0 (00)	-	287.904	0.000<0.001
2	Do you know that medical devices can cause adverse events?	215 (70.04)	92 (29.96)	-	303 (98.7)	4 (1.3)	-	95.616	0.000<0.001
3	Are you aware about the Materiovigilane programme of India (MvPI) to monitor adverse events due to medical devices?	61 (19.86)	246 (80.14)	-	293 (95.44)	14 (4.56)	-	359.061	0.000<0.001
4	Do you know where is the National Collaborating Centre of MvPI located?	54 (17.59)	52 (16.94)	201 (65.47)	272 (88.6)	30 (9.77)	5 (1.63)	338.167	0.000<0.001

5	Do you know the risk based classification of medical devices? (CDSCO)	66 (21.50)	241 78.50)	-	285 (92.83)	22 (7.17)	-	319.002	0.000<0.001
6	Who all can report adverse events due to medical devices?	171 (55.7)	136 (44.3)	-	274 (89.25)	33 (10.75)	-	86.616	0.000<0.001
7	Have you seen the Medical Deviceinduced Adverse Event (MDAE) reporting form?	51 (16.6)	256 (83.4)	-	280 (91.2)	27 (8.8)	-	343.736	0.000<0.001
8	Which of the following events should not be reported?	131 (42.67)	176 (57.33)	-	215 (70.03)	92 (29.97)	-	46.721	0.000<0.001
9	Do you think medical devices can cause adverse events in patients?	247 (80.46)	60 (19.54)	-	302 (98.37)	5 (1.63)	-	52.048	0.000<0.001
10	Is Reporting medical device adverse event (MDAE) is a part of duty of healthcare professionals?	251 (81.76)	56 (18.24)	-	299 (97.4)	8 (2.6)	-	40.189	0.000<0.001
11	Do you think reporting of any adverse events associated with medical device is necessary?	254 (82.74)	53 (18.24)	-	298 (97.07)	9 (2.93)	-	34.733	0.000<0.001
12	Do you think reporting of adverse event due to medical devices will enhance patient safety?	258 (84.04)	49 (15.96)	-	299 (97.4)	8 (2.6)	-	32.509	0.000<0.001
13	Are you willing to report a medical device induced adverse event?	231 (75.24)	76 (24.76)	-	290 (94.46)	17 (5.54)	-	44.111	0.000<0.001
14	Should materiovigilance be taught in detail to medical professionals?	248 (80.78)	59 (19.22)	-	296 (96.42)	11 (3.58)	-	37.150	0.000<0.001

DISCUSSION

Healthcare professionals have been using medical devices for years to benefit patients. However, the practice of reporting Medical Device-Associated Adverse Events (MDAE) in India is still in its early stages, with limited studies exploring the awareness of medical professionals about materiovigilance. Therefore, this study was conducted to assess the effectiveness of an awareness and sensitization program

aimed at healthcare professionals in a tertiary care teaching institute.

In this study, we analyzed the impact of an educational intervention on the knowledge, attitude, and practice of materiovigilance among healthcare professionals. The findings reveal significant gaps in knowledge prior to the intervention and substantial improvements following the program, highlighting the need for ongoing education in this area.

Before the intervention, 63.84% of participants were unaware of materiovigilance, and 29.96% did not recognize that medical devices could cause adverse events. After the intervention, 100% of participants understood materiovigilance, marking a 36.16% increase. Additionally, knowledge about the Materiovigilance Programme of India (MvPI) increased from 19.86% to 95.44% (75.58% improvement), and awareness of the National Collaboration Centre's location improved from 16.94% to 88.6% (71.66% increase). The proportion of participants familiar with the risk-based classification of medical devices rose from 21.5% to 92.83%, representing a 71.33% increase, indicating a substantial boost in knowledge.

Regarding attitude, most participants (80.46%) initially recognized that medical devices could cause adverse events, and 81.76% agreed that reporting such events was their responsibility. Post-intervention, 97.4% of participants acknowledged the importance of reporting adverse events (16.64% increase), with 94.46% expressing their willingness to report in the future (14.7% increase). Additionally, 96.42% agreed that materiovigilance should be taught in detail to healthcare professionals, a 15.64% increase from the pre-intervention response (80.78%). Although there was less awareness among professionals comparatively, participants showed positive attitude and considered as a responsibility of reporting of adverse events caused by medical devices which were observed in a similar manner in a study done by Meher BR *et al* [3] and Kurien S *et al* [10].

The practice of adverse event reporting among the participants in this study is extremely poor. Before the intervention, 83.39% of participants had never encountered adverse events related to medical devices, and 76.87% had not attended relevant workshops. After the intervention, 27.36% reported encountering adverse events, this is because the participants were able to identify adverse events related to medical devices after the educational intervention. The programme has motivated to improve the practices of HCPs towards materiovigilance.

Materiovigilance is an emerging and niche field. Only a limited number of hospitals in India are currently registered under the MvPI. The lack of awareness about materiovigilance is a significant issue. Adverse events related to medical devices place a substantial burden on healthcare systems globally. In a study done by Gagliardi *et al* [12], medicals professionals cited multiple factors such as lack of proper reporting system, absence of a conducive environment as some of the barriers for the practice of Materiovigilance. Non- reporting or underreporting of MDAE are quite prevalent. Thus, we understand that reporting culture among the HCP might get better by measures such as Continuous Medical Education, training programs or workshops.

CONCLUSION

Our study concluded that there is a significant knowledge gap regarding materiovigilance among healthcare professionals prior to the educational intervention. Many participants were unaware of key concepts, including the Materiovigilance Programme of India, the National Collaboration Centre, and the proper classification and reporting of medical device-related adverse events (MDAEs). Additionally, a substantial number of participants had never encountered or reported an MDAE, and few had attended workshops on medical device safety.

The educational intervention had a profoundly positive impact. Post-intervention results showed a remarkable increase in participants' knowledge, attitude and practice of materiovigilance. All these approaches towards safe use of medical devices will reduce the danger and risk of its use in patients and will enhance patient safety.

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Conflicts of Interest: The author declares no conflicts of interest.

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