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Knowledge, Attitude and Practice Towards Materiovigilance Among Nursing Students at a Tertiary Care Hospital - A Cross-Sectional Questionnaire Based Interventional Study

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ABSTRACT

Background: Materiovigilance is an important factor in medical device safety and awareness among healthcare providers is still substandard. Hence this programme was conducted to promote and facilitate adverse events due to medical device to safe guard and ensure the benefits of use medical device.
Methods: The interventional cross-sectional study was undertaken for two months at Bowring and Lady Curzon Hospital, attached to Shri Atal Bihari Vajpayee Medical College and Research Institute, Bangalore, India. 79 nursing students, who were chosen by simple random sampling contributed voluntarily. Data were gathered with a structured and validated questionnaire on Google Forms prior to and after an educational intervention. The questionnaire evaluated on knowledge (9 Multiple Choice Questions), attitude (3 Yes/No questions), and practice (4 Yes/No questions). Descriptive statistics and chi square test. ($p < 0.05$ was regarded as significant) were used for statistical analysis.
Results: After the intervention, participants demonstrated statistically significant improvement in majority of the parameters. Specifically, recognition of the MvPI acronym improved from 22% to 99% ($p = 0.0001$), and familiarity with correct reporting form improved from 28% to 73% ($p = 0.0001$). Attitudes also significantly improved, with perception of the necessity of reporting adverse events rising from 42% to 90% ($p = 0.0001$). Practice-based outcomes were diverse; while the incidence of adverse drug reactions was consistent (24% to 27%; $p = 0.71$), exposure to formal training increased significantly from 15% to 99% ($p = 0.0001$) and reading literature on the topic improved from 18% to 35% ($p = 0.01$).
Conclusion: The educational intervention significantly improved knowledge and attitude of nursing students regarding Materiovigilance, with modest gains in practice-related behaviour. Incorporation of such training into nursing educational curricula will enhance future healthcare professionals' commitment towards medical device safety.

Keywords: Materiovigilance, Knowledge, attitude and practice (KAP), Nursing students, Materiovigilance Programme of India (MvPI)

INTRODUCTION

The World Health Organization (WHO) has defined a medical device as 'any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material, or similar or related article intended by the manufacturer to be used, individually or in combination, for human application in the diagnosis, prevention, monitoring, treatment, or alleviation of disease'.(1) Medical devices fall into many different risk categories, ranging from low-risk items like absorbent cotton, alcohol swabs, and surgical dressings to high-risk, life-sustaining technologies like cochlear implants and cardiac pacemakers. These devices are divided into four classes (Class A to Class D) by regulatory agencies such as the Global Harmonization Task Force (GHTF), the Medicines and Healthcare Products Regulatory Agency (MHRA), and the Central Drugs Standard Control Organization (CDSCO) based on their potential for harm, invasiveness, and intended use.(2,3)

In the modern delivery of healthcare, medical devices are now essential for the diagnosis, evaluation and therapeutic management of numerous illnesses. (4) Inspired by the Essential Medicines List (EML), the WHO created the Essential Diagnostics List (EDL) to assist nations in prioritizing diagnostic technologies that are vital to patient care due to their expanding significance in national public health systems. (5)

The global incorporation of medical devices into healthcare systems has been coupled with an alarming increase in the number of medical device–associated adverse events (MDAEs).(6) Adverse events related to devices can cause considerable morbidity and, in extreme cases, death among patients or healthcare professionals.(7) Some of the historical precedents are the recall of some medical devices like infusion pumps and intravascular catheters which were recalled because of design defects or functional failures that could result in serious injury or death.(8,9)

Medical devices must have their benefit-risk profile thoroughly assessed both before to being approved for sale and during their lifecycle through post-marketing surveillance. For systematic detection and prevention of medical device–associated adverse events (MDAEs), the concept of Materiovigilance has been introduced. Materiovigilance is a systematic approach to the identification, collection, analysis, and reporting of adverse events related to medical devices with the ultimate goal of protecting public health through prevention of recurrence'. (10)

In India, the 'Materiovigilance Program of India (MvPI)' was initiated by the Drugs Controller General on July 6, 2015, at the 'Indian Pharmacopoeia Commission (IPC), Ghaziabad'. The program tracks MDAE's encouraging reporting by healthcare providers and developing robust, evidence-based safety information. While the Central Drugs Standard Control Organisation (CDSCO) maintains regulatory oversight, the IPC serves as the national coordinating centre. (3,11)

Healthcare workers play a central role in the efficient operation of Materiovigilance systems. Their knowledge, attitudes, and practices (KAP) on reporting adverse events are essential for the early identification and control of medical device-related risks. Nevertheless, evidence suggests that a significant number of adverse events go unreported, compromising the overall efficiency of Materiovigilance efforts. (12) The major barriers to reporting are low awareness, inadequate training, and perceived additional administrative burden. (13)

For nursing students—the future workforce of the healthcare system— it is imperative to engage in Materiovigilance at the earliest

level. Training at an early level instils vital competence in identification, documentation, and reporting adverse medical device-associated events, hence, a safety culture, responsibility and clinical watchfulness. Initial exposure, though, increases not only their readiness for practice as professionals but also the promise to provide quality and patient-centred care. Even though the Materiovigilance Program of India (MvPI) was launched almost a decade back, there has been limited research documenting healthcare providers especially nurses' awareness and involvement in the program. With this knowledge gap, the current cross sectional questionnaire based interventional study was planned among the nursing students at Bowring and Lady Curzon Hospital attached to Shri Atal Bihari Vajpayee Medical College and Research Institute, Bangalore to highlight the importance of instituting Materiovigilance education in nursing education curricula by highlighting its contribution among students to become informed, responsible and active participants in patient safety and healthcare quality.

MATERIALS & METHODS

This interventional cross-sectional study was conducted over a period of two months among nursing students at Bowring and Lady Curzon Hospital, attached to Shri Atal Bihari Vajpayee Medical College and Research Institute, Bangalore, India.

Inclusion and Exclusion Criteria

- Inclusion criteria: Nursing students who were willing to participate and were available for both pre- and post-intervention assessments.
- Exclusion criteria: Students who failed to complete either the pre-intervention or post-intervention questionnaire.

Based on a previous study by Sivagourounadin et al. (14), which reported 42% knowledge regarding Materiovigilance among nurses, the minimum required sample size after adjusting for a 10% potential drop out, was set at 79. A simple random sampling method was used to provide for unbiased selection of participants.

This study was commenced following ethical clearance from the Institutional Ethics Committee of Shri Atal Bihari Vajpayee Medical College and Research Institute. After informed consent.

A structured, pre-tested questionnaire was adapted and updated from previous studies (10,12,14,15,16) and shared digitally using Google Forms among the study participants.

For 'Pre- Intervention assessment', a Google Form link to the baseline questionnaire was shared with participants to assess their existing Knowledge, Attitudes, and Practices (KAP) related to Materiovigilance. Following the pre-test, the participants attended an educational session focused on the concept of Materiovigilance, the importance of adverse event reporting, and an overview of the Materiovigilance Programme of India (MvPI). After the training session, for 'Post Intervention assessment', the same questionnaire was redistributed via Google Forms to assess changes in KAP following the intervention. Only participants who completed both the pre- and post-intervention questionnaires were included in the final analysis.

For ensuring confidentiality, participant's identities were anonymized and no personal information was gathered. A unique identifier was given to each participant for data management, and all the information was placed in a safe, password-protected database which could be accessed only by the research team.

The knowledge was tested through a set of nine multiple choice questions aimed at measuring participant's knowledge of Materiovigilance principles. All correct answers were given a score of 1. The resulting total knowledge score for every participant varied between 0 and 9. In order to classify general knowledge levels, the median knowledge score was computed. Individuals whose score was on or above the median were deemed to have sufficient knowledge, while participants with a score less than the median were viewed as lacking

adequate knowledge. Similarly, the attitude category had three dichotomous (Yes/No) questions designed to measure participant's attitudes towards the significance and applicability of Materiovigilance. Every positive response, expressing a positive attitude, was assigned 1 point, whereas a negative response was assigned 0 points. More points represented a more positive attitude towards Materiovigilance. Descriptive analysis was employed to report the findings of attitude. The practice section had four closed-ended (Yes/No) questions, assessing the participant's involvement in Materiovigilance activities, such as adverse drug reaction reporting practices. For each "Yes," the score was 1, while each "No" received a score of 0. Higher cumulative score indicated more active or preferable practice behaviours concerning medical device safety.

Data was analysed using SPSS 26.0 software. The level of significance was set at $p<0.05$. Descriptive statistics was performed and Chi square test was used to assess the association between change in the pre- and post-intervention scores.

RESULT

An interventional cross-sectional study was carried out for two months at Bowring and Lady Curzon Hospital, which is a teaching hospital attached to Shri Atal Bihari Vajpayee Medical College and Research Institute, Bangalore, India. The study included 79 nursing students who agreed to participate and were available for pre- and post-intervention data collection.

Knowledge

Analysis of post-intervention noted a statistically significant improvement in the knowledge of participants on medical device vigilance (Materiovigilance). Knowledge of the Medical Device Reporting (MDR) system increased significantly from 20% before intervention to 59% after intervention ($p = 0.0001$). Proper identification of the acronym "MvPI" (Materiovigilance Programme of India) improved from 22% to 99% ($p = 0.0001$), and knowledge about the full form of MDMC (Medical Device Monitoring Centre) improved from 15% to 99% ($p = 0.0001$). Likewise, awareness of the main aim of MvPI grew from 37% to 81% ($p = 0.0001$). Identification of the right department to report adverse events improved from 35% to 94% ($p = 0.0001$), while identification of the person authorized to report such events improved from 29% to 95% ($p = 0.0001$). Awareness of the location of the National Coordinating Centre for MvPI improved from 22% to 73% ($p = 0.0001$), and knowledge of the national monitoring program for device-related adverse events increased from 24% to 82% ($p = 0.0001$). Identification of the correct reporting form finally improved from 28% to 73% ($p = 0.0001$), showing the intervention's significant effect on enhancing theoretical knowledge. (Table 1) (Figure 1)

		Pretest (n=79)	Percentage	Post test (n=79)	Percentage	P -value
Medical Device Reporting (MDR) system in India?	Correct Response	16	20%	47	59%	0.0001*
	Incorrect response	63	80%	32	41%	
What is the 1 (MvPI)?	Correct Response	17	22%	78	99%	0.0001*
	Incorrect response	62	78%	1	1%	
What is the full form of MDMC?	Correct Response	12	15%	78	99%	0.0001*
	Incorrect response	67	85%	1	1%	
What is the primary goal of the 1 (MvPI)?	Correct Response	29	37%	64	81%	0.0001*
	Incorrect response	50	63%	15	19%	
Which department is the center for reporting medical device adverse events?	Correct Response	28	35%	74	94%	0.0001*
	Incorrect response	51	65%	5	6%	
	Correct Response	23	29%	75	95%	0.0001*

Who can report medical device adverse events?	Incorrect response	56	71%	4	5%	
Where is the National Coordinating Centre for MvPI located?	Correct Response	17	22%	58	73%	0.0001*
	Incorrect response	62	78%	21	27%	
What is the current program for monitoring adverse events caused by medical devices in India?	Correct Response	19	24%	65	82%	0.0001*
	Incorrect response	60	76%	14	18%	
What is the reporting form called for adverse events related to medical devices in India?	Correct Response	22	28%	58	73%	0.0001*
	Incorrect response	57	72%	21	27%	

Table 1: Comparison of knowledge

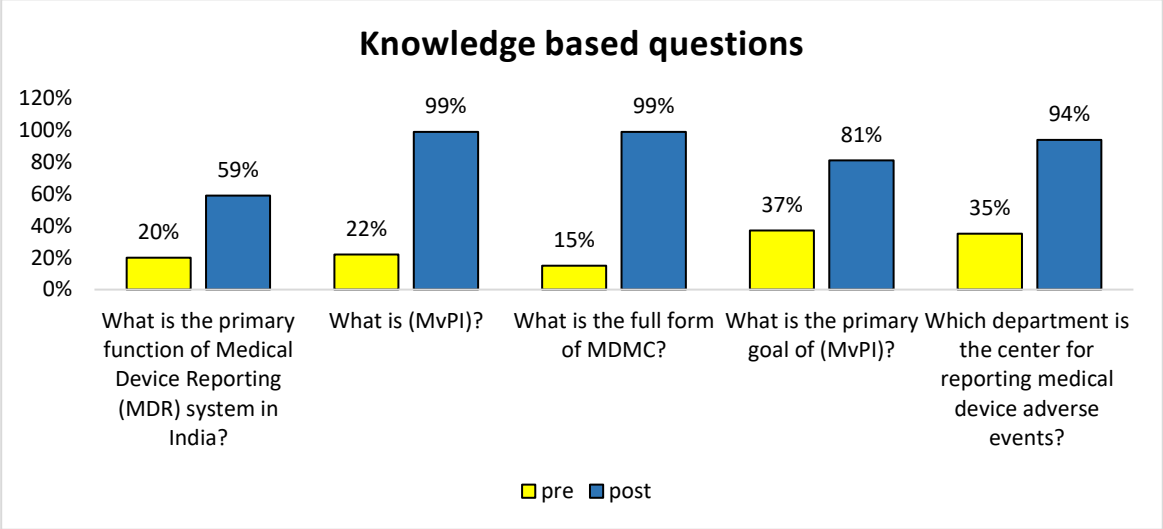

Figure 1A: Response to knowledge-based questions (correct response)

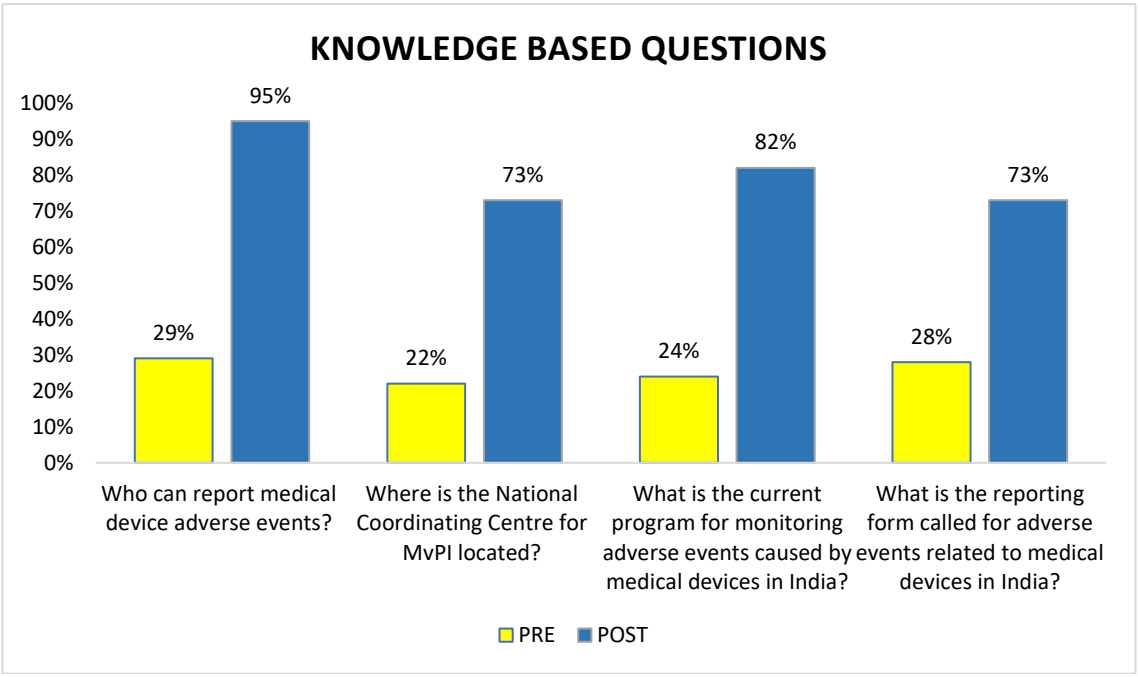

Figure 2B: Response to knowledge-based questions (Correct Response)

Attitude

Participants attitude towards medical device safety and adverse event reporting also showed significant change. The percentage of students who thought reporting adverse drug reactions is needed increased from 42% to 90% after the intervention (p = 0.0001). Initially, a large percentage of participants did not identify the obligation to report adverse drug reactions (ADRs) related to medical devices. Prior to the intervention, just 19% (15 out of 79) answered correctly, admitting that ADR reporting for medical devices is not seen as an obligation by the majority of participants. After the intervention, this increased to 51% (40 out of 79), showing a dramatic change in perception. The change observed was statistically significant (p = 0.0001), which indicates the success of the educational intervention in eliminating misconceptions regarding ADR reporting duties involving medical devices. The belief in the need for reporting of even minor events related to devices rose from 23% to 51% (p = 0.0001). These changes demonstrate a significant change in ethical and professional attitudes toward Materiovigilance. (Table 2) (Figure 2)

		Pretest (n=79)	percentage	Post test (n=79)	percentage	P Value
Do you think reporting of any adverse events associated with medical devices is necessary?	Positive Response (Yes)	33	42%	71	90%	0.0001*
	Negative Response (No)	46	58%	8	10%	
Do you think reporting of ADRs due to medical devices is an obligation?	Positive Response (No)	15	19%	40	51%	0.0001*
	Negative Response (Yes)	64	81%	39	49%	
Should the reporting of minor adverse events relate to medical devices be mandatory?	Positive Response (Yes)	18	23%	40	51%	0.0001*
	Negative Response (No)	61	77%	39	49%	

Table 2: Comparison of attitude

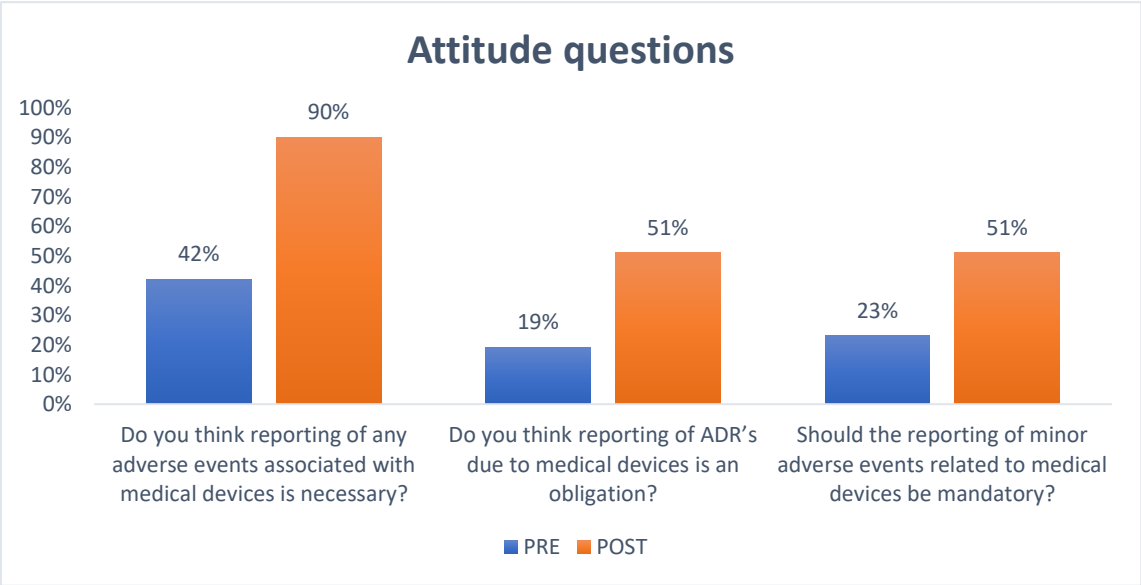

Figure 3: Response to attitude-based questions (Correct Response)

Practice

Outcomes related to practice were with mixed findings. The proportion of respondents who had experienced a Materiovigilance-related adverse event remained mostly unchanged (24% before vs.

27% after the intervention; p = 0.71). Notably, those who had reported such events fell slightly from 39% to 27%, but this was not a statistically significant change (p = 0.09). This reduction may be attributed to improved conceptual clarity on Materiovigilance, resulting in more accurate and discerning responses. However, recognition of exposure to formal training in Materiovigilance showed a striking increase—from 15% prior to the intervention to 99% subsequently (p = 0.0001). In contrast, the percentage of participants who had read any article on the topic showed minimal change (37% before vs. 39% after), and this difference was not statistically significant (p = 0.87), indicating that independent reading remained largely stable despite the intervention. (Table 3) (Figure 3)

		Pretest (n=79)	Percentage	Post test (n=79)	Percentage	p value
Have you ever encountered any adverse drug reaction due to a medical device during your practice?	Yes	19	24%	21	27%	0.71
	No	60	76%	58	73%	
If yes, have you reported it?	Yes	31	39%	21	27%	0.09
	No	48	61%	58	73%	
Have you ever attended any training or workshop specifically focused on Materiovigilance?	Yes	12	15%	78	99%	0.0001*
	No	67	85%	1	1%	
Have you ever read any article on Materiovigilance?	No	50	63%	48	61%	0.87
	Yes	29	37%	31	39%	

Table 3: Comparison of Practice

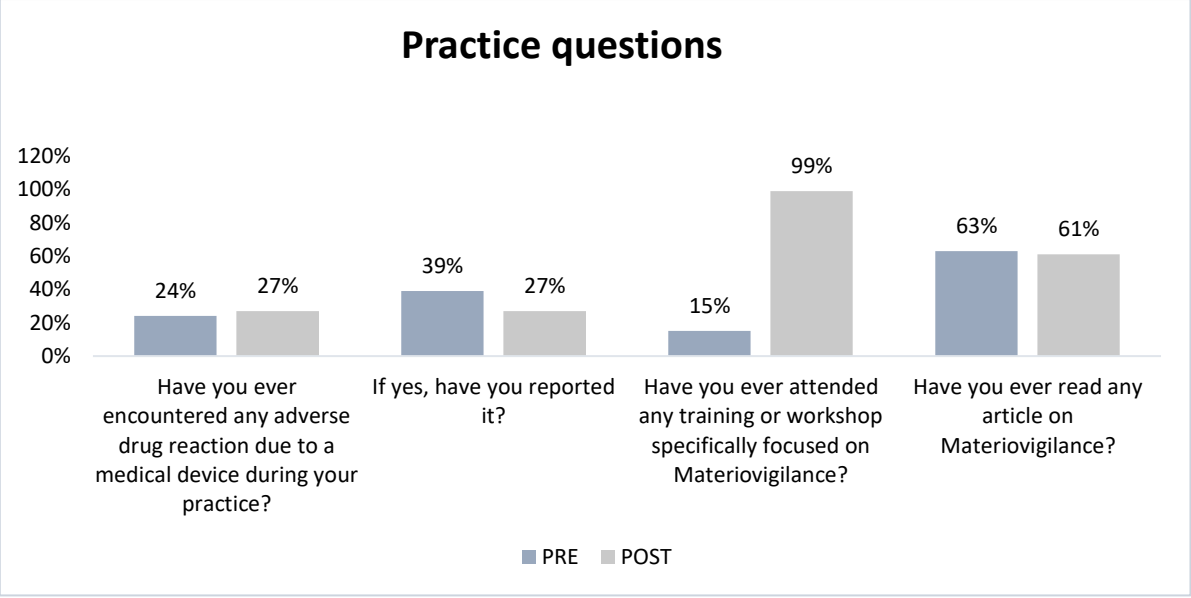

Figure 4: Response to practice-based questions (Correct Response)

DISCUSSION

This interventional cross-sectional study was conducted over two months at Bowring and Lady Curzon Hospital attached to Shri Atal Bihari Vajpayee Medical College and Research Institute, Bangalore, India, targeting 79 nursing students selected via simple random sampling. A pre-tested, structured KAP questionnaire was administered before and after an educational session on Materiovigilance. Knowledge was assessed via nine MCQs, attitude through three Yes/No items, and practice via four closed-ended questions.

In the knowledge section, each of the nine questionnaire items showed significant gains

following the intervention. Awareness of the Medical Device Reporting (MDR) system rose from 20% to 59%, indicating improved understanding of national surveillance mechanisms. Meher et al. similarly reported low initial awareness among healthcare providers, with a mean score of 2.09 ± 1.06, emphasizing the need for education[3]. Recognition of the Materiovigilance Programme of India (MvPI) acronym increased markedly from 22% to 99%, aligning with findings by Sivagourounadin et al., who observed 56% pre-existing awareness among nurses[14]. Knowledge regarding the full form of MDMC improved from 15% to 99%. A similar increase was noted by Manna et al., who emphasized the role of focused training in enhancing conceptual clarity among healthcare personnel[10].

Understanding of the core objective of MvPI improved from 37% to 81%, which mirrors outcomes reported by Panchal et al., where structured sessions helped understanding the objectives of Materiovigilance among medical practitioners[16]. Familiarity with the appropriate department for reporting improved from 35% to 94%, suggesting that participants gained clearer insights into institutional responsibilities. Knowledge of who is authorized to report adverse events improved from 29% to 95%, showing that the intervention successfully addressed misconceptions regarding reporting authority. Mohamed et al, also documented a similar post-training shift in awareness regarding the roles of various healthcare providers in the reporting process[15].Recognition of the location of the National Coordinating Centre (IPC, Ghaziabad) also rose, from 22% to 73%, which resonates with Meher et al.'s findings that only one-third of participants initially identified IPC as the coordinating body[3]. Awareness of the existing national monitoring program improved from 24% to 82%, a trend also seen in the study by Alsohime et al., where baseline knowledge of monitoring systems among ICU staff was limited[17]. Lastly, the correct identification of the standard reporting form improved from 28% to 73%, a notable change also observed in Gujarat-based training programs by Panchal et al.[16]. These results demonstrate the effectiveness of the educational intervention in bridging theoretical knowledge gaps among future healthcare professionals.

In the attitude domain, all three questions showed a considerable positive shift. Belief in the necessity of reporting adverse events increased from 42% to 90%, supporting findings from Mohamed et al., where staff attitudes changed significantly following sensitization[15]. The number of respondents who correctly indicated that reporting such events is not legally mandatory but ethically necessary grew from 19% to 51%, suggesting improved ethical awareness. Comparable trends were reported by Sivagourounadin et al., who observed that proper training positively influenced perceptions of professional accountability[14]. The belief that even seemingly minor device-related incidents should be reported increased from 23% to 51%, reflecting a more safety-conscious attitude. Manna et al. also found that post-training, healthcare workers were more inclined to recognize the significance of minor incidents[10]. These improvements highlight a marked change in student's mindset, suggesting enhanced responsibility and commitment toward patient safety.

In terms of practice, the impact of the intervention was more variable. The proportion of students who had encountered adverse events related to medical devices remained fairly stable (24% to 27%), reflecting actual clinical exposure rather than awareness limitations. This is consistent with findings from Alsohime et al., who reported a low incidence of self-reported adverse events despite reasonable knowledge levels[17]. Interestingly, the number of students who reported adverse events dropped slightly from 39% to 27%, This could indicate that the training improved their understanding of what qualifies as a reportable incident, leading to more accurate self-reporting.

Panchal et al. similarly noted shifts in reporting behaviour after educational interventions[16]. A notable finding was the sharp increase in participants who had attended training sessions on Materiovigilance, rising from 15% to 99%, affirming the role of structured instruction in improving exposure and preparedness, as also noted by Meher et al.[3]. In addition, there was a minimal rise in the number of students who had engaged with academic literature on Materiovigilance, increasing from 37% to 39% after the intervention. Similar patterns were noted by Ahmad et al., who reported that without structured guidance or institutional reinforcement, healthcare professionals often exhibit limited motivation to independently explore literature on safety reporting and related practices[12].

These results are consistent with a research at the All India Institute of Medical Sciences in Bhubaneswar, Odisha, which found that medical professionals had a baseline mean knowledge score of 2.09 ± 1.06, indicating poor awareness of materiovigilance.[3] Furthermore, 297 intensive care unit (ICU) nurses in Saudi Arabia participated in a questionnaire-based assessment that found that participants had little knowledge about medical device-associated adverse events (MDAEs).[17] Together, these results highlight the necessity of organized instructional programs around the world to improve healthcare workers' comprehension and interaction with Materiovigilance systems.

The results show that the educational intervention was successful in raising awareness and encouraging participation in Materiovigilance, as evidenced by a statistically significant change in knowledge, attitude, and practice across all domains. Nirmalya Manna et al[10]. provided support for this by stressing that visual aids like instructional posters can be used to successfully promote targeted training programs for reporting medical device-associated adverse events (MDAEs). Additionally, incorporating workshops, continuing medical education (CME) sessions, and structured training programs significantly raise awareness levels among healthcare personnel. One proactive way to encourage early and ongoing engagement among future practitioners may be to incorporate medical device safety and Materiovigilance concepts into the official healthcare curriculum.

CONCLUSION

This study shows that nursing students' knowledge, attitudes, and involvement with Materiovigilance was greatly improved by a systematic educational intervention. Significant gains were seen in every domain after the intervention, demonstrating how well it worked to raise awareness and encourage a proactive approach to medical device safety. Improvements in practice-related behaviours were less impactful than the significant changes in knowledge and attitude, indicating the need for recurrent and persistent efforts to convert awareness into regular clinical practice. The study emphasizes the importance of incorporating institutional training regarding Materiovigilance to healthcare professionals in order to enhance patient safety.

Limitations

There a few limitations in this study. Firstly, as the research was conducted in a single tertiary care teaching hospital, the findings cannot be generalized to the broader population. Second, the short duration of the study period (two-month) which implies that it could not have been long enough to record persistent or long-term shifts in knowledge, attitude and. practice.

Declaration by Authors

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