Contents lists available at BioMedSciDirect Publications

International Journal of Biological & Medical Research

Journal homepage: www.biomedscidirect.com

Original Article

Evaluation of Educational Intervention to Create Awareness About Adverse Event Reporting of Medical Devices Among Medical Postgraduates and Medical Interns in a Tertiary Care Hospital – A Quasi-Experimental Pre-Test Post-Test Study

Priyanka S[1], Hamsini N[2]

Associate Professor[1], Postgraduate Resident [2].

Department of Pharmacology, Kempegowda Institute of Medical Sciences, Bangalore

A R T I C L E I N F O

Keywords:
Early Intervention
Educational
Knowledge
Surveys and Questionnaires

A B S T R A C T

Background: Materiovigilance is a critical component of patient safety and post-marketing surveillance. In routine care, medical postgraduates and interns frequently handle medical devices and are often the first to encounter device-related problems, and it is essential to strengthen their reporting systems and training strategies. **Aims and Objectives:** To assess and compare Knowledge, Attitude and Practice (KAP) regarding materiovigilance among medical postgraduates and interns, and to evaluate the effect of a structured educational intervention. **Materials and Methods:** A validated 31-item KAP questionnaire (18 knowledge, 6 attitude, and 7 practice items) was filled by the medical postgraduates and interns as a pretest. A 45-minute educational program on materiovigilance and Medical Device-Associated Adverse Event (MDAE) reporting was delivered, followed by the same questionnaire as a post-test. Data was analyzed with $P< 0.05$, considered significant. Participant satisfaction was assessed using a 5-point Likert scale. **Results:** Of the 135 participants, 59 (43.70%) were postgraduates and 76 (56.30%) were interns. Significant improvement was seen in knowledge and attitude scores post-intervention ($P< 0.05$), whereas practice scores improved only marginally ($P> 0.05$). Knowledge and attitude post-test scores were higher among interns ($P< 0.001$), with improvement in practice scores ($P< 0.05$) compared to postgraduates. High satisfaction with the educational session was reported, with an overall mean satisfaction score of 43.32±4.19. **Conclusion:** The educational intervention effectively enhanced knowledge and attitude regarding materiovigilance, but translation into practice remained limited, emphasizing the need for sustained training and institutional support. Better outcomes among interns suggest that early structured exposure may foster stronger engagement with MDAE reporting.

© Copyright 2026 BioMedSciDirect Publications IJBMR -ISSN: 0976:6685.

INTRODUCTION

"Materiovigilance is the study of adverse events associated with the use of medical devices. It deals with the close monitoring of medical devices after the post-marketing phase". A well-structured vigilance system is the backbone of a robust regulatory framework, ensuring the quality and promoting the safe use of medical devices. [1] A medical device, as defined by the WHO, is any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material, or similar article intended by the manufacturer to be used, alone or in combination, for a medical purpose.

Medical devices have been used for patient care since time immemorial. Still, the concept of Medical Device-Associated Adverse Event (MDAE) reporting is relatively new in India, and there is hardly any data available in the public domain regarding the awareness and attitude of medical practitioners about the same. [2]

The Materiovigilance Programme of India (MvPI) was launched by the Drugs Controller General of India (DCGI) at the Indian Pharmacopoeia Commission, Ghaziabad, on July 6, 2015.[3]

***Corresponding author:**

Dr. Hamsini N.*
Postgraduate student, Department of Pharmacology,
Kempegowda Institute of Medical Sciences,
Bangalore - 560070
Email: nhamsini@gmail.com
ORCID number: 0009-0000-4096-7089

How to cite this article:

Priyanka S, Hamsini N. Evaluation of Educational Intervention to Create Awareness About Adverse Event Reporting of Medical Devices Among Medical Postgraduates and Medical Interns in a Tertiary Care Hospital – A Quasi-Experimental Pre-Test Post-Test Study. Int J Biol Med Res. 2026; 17(4): 0000-0000.

Received:05 June 2026 Accepted : 02 September 2026 Published : 03 October 2026

IJBMR -ISSN: 0976:6685. ©Copyright 2026. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).
Published by BioMedSciDirect Publications

The primary objective of this program is to monitor MDAEs, raise awareness among healthcare professionals about the importance of reporting MDAEs, and generate independent, credible, evidence-based safety data on medical devices to share with stakeholders.[4] Healthcare professionals, biomedical engineers, pharmacists, nurses, technicians, and hospital infrastructure managers, or even patients themselves, can report adverse events associated with the medical devices and it constitutes an act of moral responsibility to safeguard public health. Post-marketing vigilance system for medical devices is not as vigorous as for drugs in India. [5] Materiovigilance is an emerging field similar to Pharmacovigilance, requiring more propaganda among the right recipients.[3]

Many studies have shown that a significant proportion of adverse events related to medical devices remain underreported, which can hinder the effectiveness of materiovigilance programs. So, in order to improve the participation of healthcare professionals in spontaneous reporting, it might be necessary to design strategies that modify both the intrinsic (Knowledge, attitude, and practice- KAP) and extrinsic (relationship between the physician and their medical devices, the health system, and the regulators) factors. [6]

Also, among the healthcare providers (HCPs), the lower strata who come in contact with the medical devices are the postgraduates and interns. Thus, this study is conducted to assess the KAP about materiovigilance among medical postgraduates and interns to evaluate the impact of this educational intervention with a pre- and post-test method.

OBJECTIVES:

1.To assess the KAP among medical postgraduates and interns about Medical Device-Associated Adverse Events (MDAEs).

2.To evaluate the impact of educational program for improving the awareness about the same among the medical postgraduates and interns.

3.To measure participant satisfaction with the educational program.

MATERIALS AND METHODS:

This is a prospective questionnaire-based quasi-experimental pre-test post-test study conducted at a tertiary care teaching hospital. After obtaining ethical approval from the Institutional Ethics Committee (IEC), the study was conducted. The study subjects enrolled were all medical postgraduates from various specialties and medical interns undertaking compulsory rotatory internships at our institute in the year 2023-2024. Informed consent was taken from the study subjects.

A well-designed, structured, and validated KAP survey questionnaire about Materiovigilance was prepared to obtain feedback from the study subjects. The questionnaire consisted of 31 Multiple Choice Questions (MCQs). Out of those 31 questions, 18 questions were Knowledge-based (n=18), 6 questions were Attitude-based (n=6), and 7 questions were Practice-based (n=7). The Attitude and Practice questions were of "YES" or "NO" format and Knowledge questions were of multiple- choice format.

The subjects were given pre-test questionnaire forms, and they were given half an hour to answer the questions, after which the completed forms were collected. This pre-test session was followed by a 45- minute educational program using a presentation highlighting the definition, significance of Materiovigilance Program, MDAEs and their prevalence, cause and how to mitigate them efficiently through appropriate reporting. All the doubts pertaining to this topic were cleared at the end of the presentation, following which the students were given post-test forms similar to the pre-test forms, which were collected at the end. The pre-test and the post-test responses of both the study groups were compiled in an Excel sheet and were statistically analysed.

Participant satisfaction with the educational intervention was evaluated using a 10-item structured questionnaire based on a 5-point Likert scale (1= strongly disagree to 5= strongly agree).[7] The questionnaire assessed clarity of objectives, relevance of content, usefulness of examples, speaker effectiveness, motivation to report, confidence to report, resource availability and overall satisfaction. The pre-test and the post-test responses of both the study groups were compiled in an Excel sheet and were statistically analysed.

STATISTICAL ANALYSIS:

The two study groups in this study were medical postgraduates and interns. Gender distribution between the two groups was compared using Pearson's Chi-square test, whereas age was compared using an unpaired Student's t-test. Age was represented as mean ± Standard deviation (SD). The pre-test and post-test responses were recorded as both numbers and percentages. Paired Student's t-test was used for comparing the pre- and post-test scores within the study groups, whereas unpaired Student's t-test was used for comparing the scores between the two groups. The statistical significance was considered as $P < 0.05$ and a 95% Confidence interval. Individual item participant satisfaction scores were presented as mean ±SD, median (IQR) and percentage agreement (sum of "agree" and "strongly agree" responses). Total satisfaction score (range: 10-50) was calculated by summing all items. Interpretation categories were: very high (41-50), high (31-40), moderate (21-30), and low (< 20) satisfaction.

RESULTS:

Table I: Demographic characteristics: Age and Gender distribution across the groups

PARAME-TERS	**POST-GRAD-UATES (n=59)**	**INTERNS (n=76)**	**TOTAL n=135**	**P-VALUE**
GENDER				
MALES	26 (44%)	32 (42%)	58 (43%)	0.8203
FEMALES	33 (56%)	44 (58%)	77 (57%)	
AGE(in years)				
24	5	24	29 (21.48%)	
25	6	16	22 (16.3%)	
26	6	11	17 (12.6%)	
27	6	8	14 (10.37%)	
28	8	7	15 (11.11%)	
29	11	7	18 (13.33%)	
30	6	3	09 (6.67%)	
31	3	0	03 (2.22%)	
32	4	0	04 (2.96%)	
33	1	0	01 (0.74%)	
34	1	0	01 (0.74%)	
35	2	0	02 (1.48%)	
Mean ± SD	**28.29 ± 2.74**	**25.88 ± 1.84**		**< 0.001**

The subjects included in this study were 59 (43.70%) postgraduates and 76 (56.3%) interns. The gender and age distribution (demographic characteristics) across both groups is depicted in Table I. Among postgraduates, 33 (56%) were females and 26 (44%) were males, and among Interns, 44 (58%) were females and 32 (42%) were males. The total number of males in this study was 58 (43%), and females were 77 (57%). There were more female participants than male participants. The P-value =0.8203 with a chi-square test value of 0.0519 for gender distribution among both the groups which is not statistically significant (P>0.05), stating that the gender is equally distributed among both the groups. The mean ages of the postgraduates and interns were 28.29±2.74 years and 25.88±1.84 years, respectively.

Table II: Analysis of pre-test and post-test responses of Knowledge-based questions amongst the Postgraduates (n=59) and Interns (n=76)

Sl. No.	Questions	Response	Pre-test Response Postgraduates (%)	Post-test Response Postgraduates (%)	Pre-test Response Interns (%)	Post-test Response Interns (%)
	Knowledge-based questions					
1	What according to you is not a Medical Device?	Correct response	45 (76.27%)	50 (84.75%)	45 (59.2%)	50 (65.79%)
		Wrong response	14 (23.73%)	9 (15.25%)	31 (40.8%)	26 (34.21%)
2	All these are IPC (Indian Pharmacopoeia Commission) services except:	Correct response	25 (42.37%)	37 (62.71%)	34 (44.74%)	51 (67.11%)
		Wrong response	34 (57.63%)	22 (37.29%)	42 (55.26%)	25 (32.89%)
3	Medical devices are classified based on:	Correct response	08 (13.56%)	18 (30.51%)	10 (13.16%)	25 (32.9%)
		Wrong response	51 (86.44%)	41 (69.49%)	66 (86.84%)	51 (67.1%)
4	Which year was Materiovigilance officially launched?	Correct response	23 (38.98%)	35 (59.3%)	32 (42.11%)	56 (73.7%)
		Wrong response	36 (61.02%)	24 (40.7%)	44 (57.89%)	20 (26.3%)
5	Following are the types of Adverse events related to Medical Devices except:	Correct response	24 (40.7%)	34 (57.63%)	37 (48.68%)	49 (64.47%)
		Wrong response	35 (59.3%)	25 (42.37%)	39 (51.32%)	27 (35.53%)
6	MvPI has which state as the NCC (National Coordinating Centre) for post market vigilance of medical devices?	Correct response	22 (37.29%)	21 (35.6%)	29 (38.16%)	45 (59.21%)
		Wrong response	37 (62.71%)	38 (64.4%)	47 (61.84%)	31 (40.79%)
7	Field Safety Notice (FSN) is sent to:	Correct response	10 (16.95%)	11 (18.6%)	05 (6.58%)	20 (26.31%)
		Wrong response	49 (83.05%)	48 (81.4%)	71 (93.42%)	56 (73.69%)
8	Serious adverse event means all except:	Correct response	45 (76.27%)	49 (83.05%)	60 (78.95%)	59 (77.63%)
		Wrong response	14 (23.73%)	10 (16.95%)	16 (21.05%)	17 (22.37%)
9	Shelf life associated with Medical Devices are?	Correct response	43 (72.88%)	35 (59.3%)	45 (59.21%)	53 (69.74%)
		Wrong response	16 (27.12%)	24 (40.7%)	31 (40.79%)	23 (30.26%)
10	Post Marketing Surveillance of Medical Devices means:	Correct response	43 (72.9%)	48 (81.36%)	60 (78.95%)	60 (78.95%)
		Wrong response	16 (27.1%)	11 (18.64%)	16 (21.05%)	16 (21.05%)
11	Recall about Medical devices is related to:	Correct response	23 (38.98%)	27 (45.76%)	42 (55.26%)	51 (67.10%)
		Wrong response	36 (61.02%)	32 (54.24%)	34 (44.74%)	25 (32.9%)
12	Roles and responsibilities of the MDMCs are all except:	Correct response	27 (45.76%)	34 (57.63%)	36 (47.37%)	50 (65.78%)
		Wrong response	32 (54.24%)	25 (42.37%)	40 (52.63%)	26 (34.22%)

13	Who is the National Regulatory Authority of MvPI in India?	Correct response	21 (35.6%)	42 (71.19%)	32 (42.10%)	58 (76.32%)
		Wrong response	38 (64.4%)	17 (28.81%)	44 (57.9%)	18 (23.68%)
14	The following can report the adverse event except:	Correct response	35 (59.32%)	44 (74.57%)	62 (81.58%)	63 (82.9%)
		Wrong response	24 (40.68%)	15 (25.43%)	14 (18.42%)	13 (17.1%)
15	Identifying MDAE (Medical Device Adverse Event) by:	Correct response	09 (15.2%)	24 (40.7%)	20 (26.32%)	20 (26.32%)
		Wrong response	50 (84.8%)	35 (59.3%)	56 (73.68%)	56 (73.68%)
16	Timeline to report serious adverse event:	Correct response	14 (23.73%)	34 (57.63%)	08 (10.53%)	30 (39.47%)
		Wrong response	45 (76.27%)	25 (42.37%)	68 (89.47%)	46 (60.53%)
17	Ways of reporting a Medical Device Adverse Event (MDAE) are all except:	Correct response	20 (33.9%)	34 (57.63%)	34 (44.74%)	54 (71.05%)
		Wrong response	39 (66.1%)	25 (42.37%)	42 (55.26%)	22 (28.95%)
18	Inhibitions in reporting a MDAE are all except:	Correct response	20 (33.9%)	27 (45.7%)	32 (42.10%)	22 (28.94%)
		Wrong response	39 (66.1%)	32 (54.3%)	44 (57.9%)	54 (71.06%)

Table III: Analysis of pre-test and post-test responses of Attitude and Practice-based questions amongst the Postgraduates (n=59) and Interns (n=76)

Sl. No.	Questions	Response	Pre-test Response Postgraduates (%)	Post-test Response Postgraduates (%)	Pre-test Response Interns (%)	Post-test Response Interns (%)
	Attitude-based questions					
1	Are you aware of what is Materiovigilance?	Yes	35 (59.32%)	56 (94.92%)	28 (36.84%)	72 (94.74%)
		No	24(40.68%)	03 (5.08%)	48 (63.16%)	04 (5.26%)
2	Do you think Medical Devices require monitoring?	Yes	58 (98.30%)	59 (100%)	76 (100%)	76 (100%)
		No	01 (1.7%)	00 (0%)	00 (0%)	00 (0%)
3	Does reporting an adverse event of the medical devices benefit the patient?	Yes	55 (93.22%)	58 (98.30%)	74 (97.37%)	73 (96.05%)
		No	04 (6.78%)	01 (1.7%)	02(2.63%)	03 (3.95%)
4	Can the severity of adverse event of medical devices lead to death of the patient?	Yes	58 (98.30%)	57 (96.61%)	74 (97.37%)	72 (94.74%)
		No	01 (1.7%)	02 (3.39%)	02 (2.63%)	04 (5.26%)
5	Have you come across any problem in the medical device in hospital set up?	Yes	41 (69.5%)	36 (61.02%)	29 (38.16%)	38 (50%)
		No	18 (30.50%)	23 (38.98%)	47 (61.84%)	38 (50%)
6	Is Materiovigilance part of Pharmacovigilance?	Yes	34 (57.63%)	41 (69.5%)	56 (73.68%)	49 (64.47%)
		No	25 (42.37%)	18 (30.50%)	20 (26.32%)	27 (35.53%)
	Practice-based questions					
7	If you encountered a MDAE will you report or not?	Yes	50 (84.75%)	54 (91.53%)	71 (93.42%)	71 (93.42%)

		No	09 (15.25%)	05 (8.47%)	05 (6.58%)	05 (6.58%)
8	Would you be willing to attend a workshop or CME on Materiovigilance?	Yes	41 (69.49%)	46 (77.97%)	48 (63.16%)	48 (63.16%)
		No	18 (30.51%)	13 (22.03%)	28 (36.84%)	28 (36.84%)
9	Have you received any formal training on MV?	Yes	11 (18.64%)	11 (18.64%)	14 (18.42%)	14 (18.42%)
		No	48 (81.36%)	48 (81.36%)	62 (81.58%)	62 (81.58%)
10	Have you used the MvPI reporting form or helpline?	Yes	20 (33.9%)	20 (33.9%)	45 (59.21%)	46 (60.53%)
		No	39 (66.10%)	39 (66.10%)	31 (40.79%)	30 (39.47%)
11	Have you discussed MDAEs in clinical meetings or ward rounds?	Yes	18 (30.50%)	18 (30.50%)	34 (44.74%)	34 (44.74%)
		No	41 (69.5%)	41 (69.5%)	42 (55.26%)	42 (55.26%)
12	Will you educate others about the significance of reporting MDAEs or not?	Yes	50 (84.75%)	54 (91.53%)	61 (80.26%)	63 (82.9%)
		No	09 (15.25%)	05 (8.47%)	15 (19.74%)	13 (17.10%)
13	Do you maintain any record of device-related issues observed during your clinical postings?	Yes	09 (15.25%)	09 (15.25%)	09 (11.84%)	09 (11.84%)
		No	50 (84.75%)	50 (84.75%)	67 (88.16%)	67 (88.16%)

Table IV a: Comparison of pre-test and post-test scores of Postgraduates

Questions	Pre-test scores Postgraduates (n=59)	Post-test scores Postgraduates (n=59)	95% CI	P-value
Postgraduates				
Knowledge-based questions	25.39±11.84	33.56±10.54	(5.55, 10.79)	< 0.001
Attitude-based questions	46.83±10.45	51.17±9.12	(2.04, 6.64)	<0.05
Practice-based questions	28.43±16.69	30.29±17.86	(-2.18, 5.90)	>0.05

Table IV b: Comparison of pre-test and post-test scores of Interns

Questions	Pre-test scores of Interns (n=76)	Post-test scores of Interns (n=76)	95% CI	P-value
Interns				
Knowledge-based questions	34.61±16.29	45.33±14.37	(7.57, 13.87)	<0.001
Attitude-based questions	56.17±20.66	63.33±14.44	(3.35, 10.97)	<0.05
Practice-based questions	40.29±21.26	40.71±21.39	(−3.94, 4.78)	>0.05

Table V: Comparison of post-test scores among the Postgraduates and Interns

Questions	Pre-test scores Postgraduates (n=59)	Post-test scores Postgraduates (n=59)	95% CI	P-value
Knowledge-based questions	33.56±10.54	45.33±14.37	[7.52, 16.02]	< 0.001
Attitude-based questions	51.17±9.12	63.33±14.44	[8.13, 16.19]	< 0.001
Practice-based questions	30.29±17.86	40.71±21.39	[3.76, 17.08]	<0.05

Table VI: Participant Satisfaction Scores after Educational Intervention (N=135) using Likert Scale

Mean ± SD	Median (IQR)	Interpretation
43.32 ± 4.19	44 (41-47)	Very high satisfaction

SD- Standard deviation
IQR- Interquartile range

The pre- and post-test responses of the postgraduates and interns were recorded both as numbers and percentages for Knowledge-based (Table II), Attitude and Practice-based (Table III) questions.

Analysis of the pre-test and post-test responses of the postgraduates as shown in Table IV a, depicts that they have answered the post-test better compared to the pre-test, in all three domains. Among the postgraduates, there was statistically significant improvement in the knowledge and attitude domains but in practice domain, there was only a slight improvement in their post-test scores. In the knowledge domain, the mean (P< 0.05) of the pre-test scores was 25.39 ± 11.84, and the post-test scores was 33.56 ± 10.54. In the attitude domain, the mean (P< 0.05) of the pre-test scores was 46.83±10.45, and the post-test scores was 51.17±9.12.

Concerning the practice domain, the mean (P> 0.05) of the pre-test scores was 28.43±16.69 and the post-test scores was 30.29±17.86.

Analysis of the pre-test and post-test scores of interns as shown in Table IV b that they have also answered the post-test better compared to the pre-test in all three domains But, concerning the practice domain, there was only a slight improvement in their post-test scores. In the knowledge domain, the mean (P< 0.05) pre-test scores were 34.61 ± 16.29, and the post-test scores were 45.33 ± 14.37. In the attitude-domain, the mean scores (P < 0.05) of pre-test were 56.17±20.66 and the post-test were 63.33±14.44, and in the practice-domain, the mean scores (P > 0.05) of pre-test were 40.29±21.26 and the post-test were 40.71±21.39

The post-test scores among the postgraduates and interns as shown in Table V, showed highly significant difference (P < 0.001) with respect to knowledge-domain. In the attitude domain also, a highly significant difference (P < 0.001) was observed among the two groups. In the practice domain also, a statistically significant difference (P< 0.05) was seen among the groups. Overall, the interns performed better than postgraduates, as their post-test scores were higher in all the three domains.

Table VI shows the satisfaction levels of participants following the educational intervention. Overall satisfaction was very high, with a mean total score of 43.32 ± 4.19 out of 50. The highest scoring parameters were the speaker's clarity of communication (mean 4.52 ± 0.55; 95.6% agreement) and improved understanding of materiovigilance (mean 4.46 ± 0.59; 93.3% agreement). Satisfaction with session duration showed the lowest mean score (4.11 ± 0.76) but remained in the high satisfaction category.

DISCUSSION:

This is a prospective questionnaire-based quasi-experimental pre-test post-test study with an educational program done among the medical postgraduates and medical interns in a tertiary care hospital about Medical Device-Associated Adverse Events (MDAEs). Out of the total study subjects (n=135), female subjects were more (57%) than the male subjects (43%), but it was not statistically significant, indicating no statistically significant difference in gender distribution between the two groups. The mean age of the postgraduates and interns was 28.29±2.74 years and 25.88±1.84 years, respectively, which depicts that it was the right time for them to learn and implement Materiovigilance, as they will be the future caregivers in the hospitals. Also, they are the ones who will be maximally exposed to the MDAEs, and an appropriate educational intervention like this will help them in handling, reporting, and mitigating risks associated with medical devices appropriately.

The pre-test and the post-test scores of postgraduates and interns showed that the intervention was highly effective in improving the participants' knowledge about materiovigilance. Concerning the attitude domain, as the post-test scores were more than the pre-test scores, it indicates that there was a positive shift in the subject's attitude about this topic. But the intervention did not produce a statistically significant result in the practice domain, pointing out that practical application may require a longer follow-up period for both the study groups.

The pre-test and the post-test scores of postgraduates and interns show that the correct responses were relatively higher in the post-test scores in all three domains among both groups. On comparing the post-test scores of both groups, the interns scored significantly higher than the postgraduates in the knowledge domain. Thus, this intervention seems to be more effective for interns in improving their knowledge. There is also a statistically significant difference in their attitude scores, suggesting that interns were showing a more positive attitude compared to postgraduates on MDAE awareness. Interns also fared well on practice-based questions. The interns thus displayed a significantly better transition of knowledge into practice, as compared to the postgraduates. Overall, interns performed better than postgraduates in all three domains- knowledge, attitude, and practice. This type of comparison of KAP within the group and across the groups through pre- and post-test surveys after an educational program is also seen in studies like Shamita Shyam Sail et al.,[8] Bhupendra Prakash Solanke et al.,[9] and Priyanka S, et al.[10]

The high participant satisfaction scores observed (Table VI) indicate that the educational session was well-received, relevant, and effectively delivered. The high percentage of agreement for improved understanding and clarity of communication suggests that the training successfully addressed critical gaps in awareness of materiovigilance and reporting procedures. These findings support previous educational research showing that interactive and targeted training significantly enhances learner engagement and perceived applicability to clinical practice. This type of analysis using a 5-point Likert scale is also seen in studies like Alsaleh FM et al.,[11] and Patidar, G.K. et al.,[12] etc.

The main advantage of a pre-test and post-test study design is that there is a directionality of the research, implying that there is testing of a dependent variable, like knowledge or attitude, before and after an intervention with an independent variable, like training or an information presentation session.[13] This type of KAP study with a pre-test and post-test design helps in assessing the impact of an intervention by measuring the participants' knowledge, attitudes, and practices before and after an intervention. This enables us to understand if the intervention has led to a positive change in these less explored areas.

Limitations:

The limitation of the present study is that the study subjects cannot be followed for a longer time to assess if they have applied their knowledge and attitude into practice concerning Materiovigilance. This study involves only Interns and postgraduates and not the medical students, professors, and other staff of the hospital. These kinds of awareness programs should not be limited only to presentations; rather, workshops, etc., should be conducted to generate greater interest in this emerging field.

Clinical Significance:

The main strength of this study is that this is one of the few studies that has a quantitative method of analyzing three domains-KAP with a predefined and validated questionnaire about Materiovigilance among the medical postgraduates and medical interns of a tertiary care hospital. Since postgraduates are newly graduated and interns will be freshly graduating, they will be open-minded to learn new evolving concepts like materiovigilance, and will help in successfully implementing them in their healthcare setup. Hence, it is a very useful way of educating them about MDAEs.

CONCLUSION:

Materiovigilance plays a very crucial role in a hospital setup, and medical devices need regular monitoring. Any failure in the medical device may take a toll on a patient's life and safety; hence, detection, assessment, reporting, and prevention of MDAE are very important. Here, the objective of increasing awareness about MDAE among postgraduates and interns proved useful. Both study groups understood the importance of materiovigilance and were expected to implement the knowledge gained through this intervention in practice which will help mitigate potential risks associated with MDAE.

AUTHOR CONTRIBUTIONS:

1st author- formed the concept, designed the study, defined the intellectual content, and conducted the literature search, manuscript editing, and manuscript review.

2nd author and corresponding author - Performed data acquisition, helped design the study, and contributed to data analysis, statistical analysis, and manuscript preparation.

ACKNOWLEDGEMENT:

We would like to sincerely thank the medical postgraduates and the interns for actively participating in the study and also the faculty of the Pharmacology department for allowing us to conduct this study.

Conflict of Interest: Nil

Sources of Funding: Nil

Ethical Approval- The research/study was approved by the Institutional Review Board at Kempegowda Institute of Medical Sciences, number KIMS/IEC/A028/M/2022.

LIST OF ABBREVIATIONS:

KAP- knowledge, attitude, and practice

MDAE- Medical Device-Associated Adverse Event

SD- Standard deviation

IQR- Interquartile range

References:

[1] Shatrunajay Shukla, Madhur Gupta, Sabitri Pandit et al. Implementation of adverse event reporting for medical devices, India. Bull World Health Organ 2020;98:206-211.

[2] Meher BR. Materiovigilance: An Indian perspective. Perspect Clin Res. 2018 Oct-Dec;9(4):175-178.

[3] Sapkota B, Palaian S, Shrestha S, Ibrahim MIM. Materiovigilance in Perspective: Understanding Its Concept and Practice in the Global Healthcare System. Ther Innov Regul Sci. 2023 Jul;57(4):886-898.

[4] Sojitra B, Patel C, Pandya S, Virani P, Shah P, Patel J, et al. Knowledge, Attitude, and Practice of Materiovigilance Among Healthcare Professionals at a Tertiary Care Teaching Hospital. Cureus. 2024 Jul 20;16(7):e64978.

[5] Saifuddin PK, Tandon M, Kalaiselvan V, Suroy B, Pattanshetti V, Prakash A, et al. Materiovigilance Programme of India: Current status and way forward. Indian J Pharmacol. 2022 May-Jun;54(3):221-225.

[6] Panchal YN, Vyas BM, Suthar KM, Shah KN. A study of assessing knowledge, attitude, and practice of materiovigilance among medical surgeons of Gujarat. Natl J Physiol Pharm Pharmacol. 2022;12(11):1792-1797.

[7] Sullivan GM, Artino AR Jr. Analyzing and interpreting data from likert-type scales. J Grad Med Educ. 2013 Dec;5(4):541-2.

[8] Sail SS, Gore A, Sayed AA, Khan MR, Swamy AHMV, Dayana BM, Nyamagoud SB. KAP analysis of the materiovigilance programme: a comparative study between M.Pharm and D.Pharm students. Int J Pharm Investig. 2025;15(2):407–16. doi:10.5530/ijpi.20250035

[9] Solanke BP, Birhare P, Sinha S, Dahiya N. A questionnaire-based study on the knowledge, attitude and practice on pharmacovigilance among pharmacists and nursing staff at teaching hospitals. Med J Armed Forces India. 2024 Dec;80(Suppl 1):S167-S173

[10] Priyanka S, Vasundara K, Girish K. A comparative study of knowledge, attitude, and practice of drug-drug interactions among interns and nurses in a tertiary care hospital. Natl J Physiol Pharm Pharmacol 2022;12(01):79-83.

[11] Alsaleh FM, Elzain M, Alsairafi ZK, Naser AY. Perceived Knowledge, Attitude, and Practices (KAP) and Fear toward COVID-19 among Patients with Diabetes Attending Primary Healthcare Centers in Kuwait. Int J Environ Res Public Health. 2023 Jan 29;20(3):2369.

[12] Patidar GK, Dhiman Y, Kumawat V. Knowledge, attitude and practice (KAP) study among Indian transfusion medicine experts regarding peer review process. VOXS. 2021; 16:68-75.

[13] Stratton SJ. Quasi-Experimental Design (Pre-Test and Post-Test Studies) in Prehospital and Disaster Research. Prehosp Disaster Med. 2019 Dec;34(6):573-574.

© Copyright 2026 BioMedSciDirect Publications IJBMR -ISSN: 0976:6685.