

Effectiveness of Educational Interventions in Enhancing Pharmacy Students KAP of Materiovigilance

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ABSTRACT

Background: The Materiovigilance Programme of India (MvPI) was launched on 6th July 2015 by the (DCGI) at the Indian Pharmacopoeia Commission, to ensure the safety and effectiveness of medical devices. With the increasing use of sophisticated medical devices in healthcare, incidents such as Serious Adverse Events (SAEs) have been reported. The study aimed to evaluate the Knowledge, Attitude, and Perception (KAP) of pharmacy students across different streams toward MvPI, using an educational intervention to enhance their involvement in patient safety and spontaneous reporting of MDAEs. **Materials and Methods:** A total of 545 participants from B Pharm, D Pharm, M Pharm and Pharm D students participated in the study. The participants' demographic details were collected, and their KAP was assessed through a 15-question survey administered before and after an educational intervention. The internal consistency and reliability of the questionnaires were evaluated using Cronbach's alpha and IBM SPSS 27.0. **Results:** The study revealed a significant improvement in KAP across all pharmacy streams post-intervention. Awareness of MvPI increased from 27.7% in the pre-test to 88.07% in the post-test. Attitude and perception also showed marked improvements, with positive responses rising from 52.85% to 72.9% in attitude and from 56.33% to 76.24% in perception. **Conclusion:** The educational intervention significantly enhanced the KAP of pharmacy students regarding MvPI. Including Materiovigilance in pharmacy curricula and promoting MDAE reporting are essential steps to adapt greater awareness and involvement in patient safety among healthcare specialists.

Keywords: Knowledge, Attitude, Perception, Materiovigilance, IPC.

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INTRODUCTION

Medical Devices (MD) plays a vital role in the diagnosis, monitoring, and management of different diseases and conditions. MD gives tremendous advantage to patients as well as stretch out the capacity of clinicians to analyse and treat different illness conditions (Mandanna *et al.*, 2023). The medical services industry depends on medical devices to guarantee patient health and give the most ideal care (Sojitra, B *et al.*, 2024). The fundamental aspect of materiovigilance is acquiring, analysing, and determining data on medical device adverse events and ensuring to avoid any potential hazards or issues linked with medical devices (Selvam *et al.*, 2024). Mv mechanisms have been initiated at the national and international levels to guarantee a thorough approach to deal with medical device wellbeing. Regulatory agencies involved

and implemented guidelines directing Mv activities, presently India is attaining the development with its own Medical Device Materiovigilance Program, initiated on July 6, 2015, at Indian Pharmacopoeia Commission (IPC) (Mandanna *et al.*, 2023). Most common and dangerous medical devices that have prompted unfortunate results incorporate breast implants, pacemakers, incubators, and artificial hips grafted into patients' bodies. While the program was established around about six years ago, insufficient studies demonstrated featuring this issue (Modi K *et al.*, 2023). Progress of any program can be judged only by doing reviews from time to time. Therefore, this study was planned to learn about the knowledge, attitude and practices among the pharmacy students and enhancing their understanding, beliefs and perceptions towards materiovigilance (Tantia, R *et al.*, 2023).

MATERIALS AND METHODS

Study site

The study was conducted at KLE College of Pharmacy, Vidyanagar, Hubballi.



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Study design

It was a cross-sectional, self-designed questionnaire-based study designed to evaluate the Knowledge, Attitude, and Perception of Materiovigilance among all the Pharmacy students.

Ethical Approval

Ethical clearance was obtained from institutional ethical committee, KLE College of Pharmacy, Hubballi. IEC No. KLECOPH/IEC/2023-24/01.

Study period

The learning was carried out for a period of 6 months in KLE College of Pharmacy, Vidyanagar, Hubballi, Karnataka.

Study criteria

Inclusion criteria

Students enrolled in various Pharmacy streams at KLE College of Pharmacy, Hubballi.

Exclusion criteria

Pilot study participants were excluded from the study and students who are not willing to contribute to the learning.

Study Procedure

A Total of 15 MvPI questionnaire were developed by the faculty of department of Pharmacy Practice, assessing three domains: Knowledge, Attitude, and Perception, each containing 5 questions. All questions within the Knowledge domain were dichotomous (coded as 'Yes' as 1 and 'No' as 0). The questions in the Attitude and Perception domains used as 5.0- score point using Likert scale indicating ('Strongly Disagree,' 'Disagree,' 'Not sure,' 'Agree,' and 'Strongly Agree,' corresponding to values 1 to 5 respectively).

Internal consistency was evaluated using IBM SPSS 27.0, and Cronbach's alpha (α) was employed, which ranges from 0 to 1. A higher alpha value indicates stronger relationships among scale items. An α falling within the range of 0.8 to 0.9 specifies a 'good internal consistency.' The form was distributed among 21 Pharmacy students as a part of a pilot survey resulting in an internal consistency α of 0.827. Hence, the MvPI questions showed acceptable internal consistency.

The prepared questionnaire was provided for the study participants and they were asked to answer the questions (pre-test). Later, a brief educational session using power point presentation on the topic Mv was provided to the study participants which included insightful information on the definitions, aim, regulatory body, history, how to report, whom to report, where to report, types of medical devices etc. After the education session, the same set of 15 questions each with 3 domains was re-distributed to the

study participants through google forms and the responses were recorded (post-test).

Statistical analysis

All the data were input into a Microsoft Excel spreadsheet. Continuous data were presented as mean \pm standard deviation. The differences between the groups were evaluated using a t-test. Suitable descriptive and inferential statistical analyses were conducted using Excel and SPSS version 27.

Sample size

Sample size is calculated using the formula;

$$N = \frac{[Z_{1-\alpha/2}]^2 p (1 - p)}{d^2}$$

where, Z is critical value,

d is allowable error,

p is sample proportion,

α is level of significance.

RESULTS

Demographic characteristics in MvPI

The study comprises 545 participants depicted in above Table 1, with a slight predominance of females (302) over males (243). The age ranges of participants from 18 to 25 and beyond, with the largest group being 21-year-olds (114 participants). This distribution highlights the age diversity within the study population in the below Figures 1 and 2.

Participants are enrolled across various levels of pharmacy education, including B Pharm, D Pharm, M Pharm, and Pharm D students. The largest cohorts include students from B Pharm 2nd year (68 participants), D Pharm 1st year (63 participants), and B Pharm 4th year (57 participants). This distribution illustrates the progression of students through their respective academic programs. A significant majority of the participants are undergraduates (410), while the remaining (135) participants are postgraduates pursuing their master's degrees, highlighting the educational diversity within the study group.

Furthermore, the parental background of the participants reveals that the majority (473 participants) come from non-medical fields, suggesting limited direct exposure to healthcare professions within their immediate family. However, a smaller subset (72 participants) has parents with medical backgrounds, which could potentially influence their familiarity with healthcare-related concepts. This contrast in parental background may offer insights into varying levels of knowledge and perspectives within the study population, by following Figures 3 and 4.

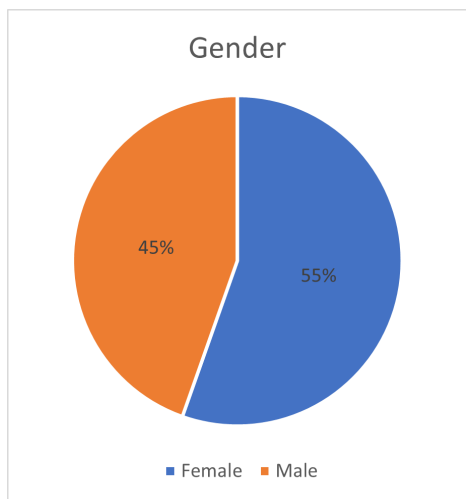


Figure 1: Gender distribution in percentage.

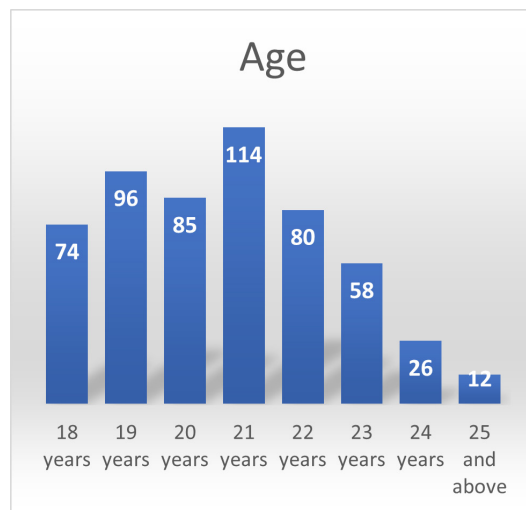


Figure 2: Age category distribution in number.

Table 1: Demographic details of Mv participants.

Demographics	Categories	n=545 (%)
Gender	Female	302 (55.41%)
	Male	243 (44.58%)
Age in years	18	74 (13.57%)
	19	96 (17.61%)
	20	85 (15.51%)
	21	114 (20.91%)
	22	80 (14.67%)
	23	58 (10.64%)
	24	26 (4.77%)
	25	12 (2.20%)
Year of study	B Pharm	208 (38.16%)
	D Pharm	123 (22.56%)
	M Pharm	60 (11.00%)
	Pharm D	154 (28.25%)
Education Level	Post Graduate	135 (24.77%)
	Under Graduate	410 (75.22%)
Parents profession	Non-medical background	473 (86.78%)
	Medical background	72 (13.21%)
Socioeconomic status	Lower class (< 1 lakh Rupees per year)	161 (29.54%)
	Lower middle class (2 to 5 lakh Rupees per year)	134 (24.58%)
	Upper class (> 10 lakh Rupees per year)	36 (6.60%)
	Upper lower class (1 to 2 lakh Rupees per year)	65 (11.52%)
	Upper middle (5 to 15 lakh Rupees per year)	149 (27.33%)
Residence	Rural	192 (35.22%)
	Urban	353 (64.77%)

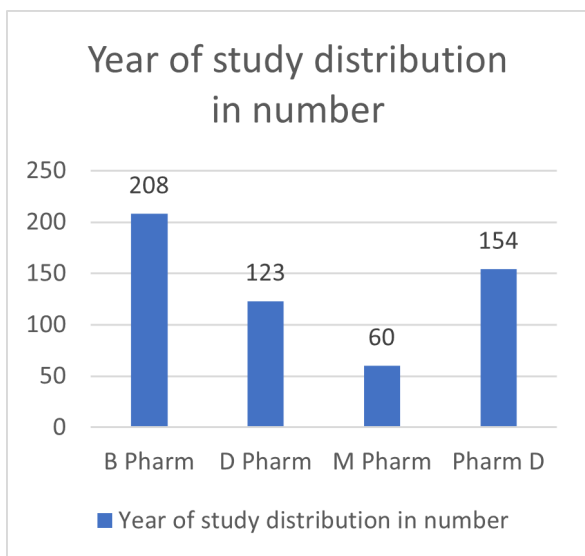


Figure 3: Year of study distribution in percentage.

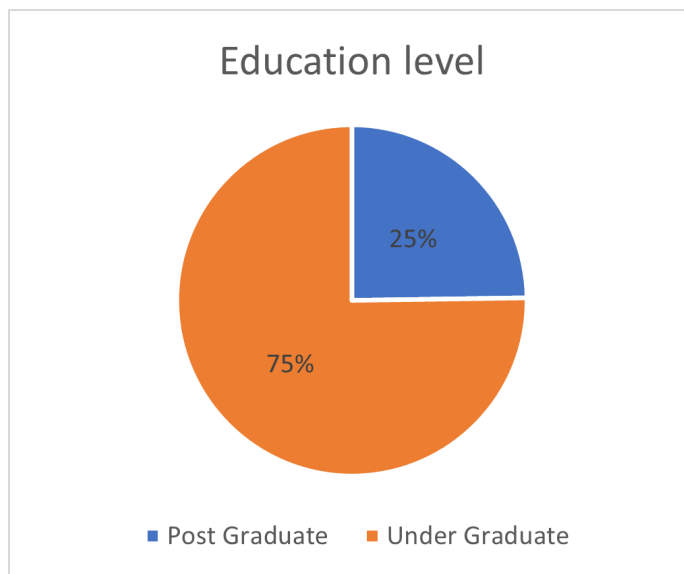


Figure 4: Education level distribution in percentage.

Table 2: Knowledge of Mv among the participants.

Sl. No.	Knowledge Based Questions	MvPI (n=545)			
		Pre [N (%)]		Post [N (%)]	
		Correct	Incorrect	Correct	Incorrect
1	Are you aware of the ongoing Materiovigilance Programme of India?	151 (27.70)	394 (88.3)	480 (88.07)	65 (11.9)
2	Are you aware that the medical devices are classified into 4 categories (Category A, Category B, Category C and Category D)?	154 (28.2)	391 (71.74)	478 (87.7)	67 (12.29)
3	Are you aware of how and whom to report the adverse events caused by the medical devices?	177 (32.4)	368 (67.5)	474 (86.9)	71 (13.02)
4	Have you come across any means/forms of reporting adverse events related to medical devices?	152 (27.8)	393 (72.11)	426 (78.1)	119 (21.83)
5	Have you come across any alerts or recall about medical devices?	145 (26.6)	400 (73.3)	396 (72.6)	131 (24.03)

The distribution across different socioeconomic categories highlights the economic diversity within the study population. Most of the participants (353) reside in urban areas, while a smaller portion (192) comes from rural regions. This urban-rural split mirrors broader trends of increasing urbanization, with more individuals concentrated in urban centers than in rural areas. These demographic insights offer a well-rounded view of the study population, encompassing factors such as gender, age, academic level, parental background, socioeconomic status, and residential location, all of which may influence participants' perspectives and experiences related to Materiovigilance.

Assessment of Knowledge, Attitude and Perception of Materiovigilance

Knowledge of Mv among the participants

The Knowledge-based section of the study shown in the above Table 2, involving 545 participants regarding the Materiovigilance Programme of India (MvPI), compares knowledge levels before (PRE) and after (POST) an intervention. This table represents responses categorized as either correct or Incorrect. Across all five questions, there's a notable improvement in knowledge post-intervention especially for Materiovigilance Programme of India (MvPI) following the intervention. Initially, only 27.7% of participants were aware of the MvPI, which increased dramatically to 88.07% post-intervention. Similarly, awareness

of the classification of medical devices improved from 28.2% to 87.7%. Knowledge about reporting adverse events caused by medical devices also saw a substantial increase, from 32.4% to 86.9%. The number of participants who encountered forms for reporting adverse events related to medical devices increased from 27.8% to 78.1%, and those who had come across alerts or recalls about medical devices increased from 26.6% to 72.6%. These results indicate a successful intervention, with marked improvements in awareness and knowledge across all measured aspects of Materiovigilance as seen in the Post-test among all the Pharmacy students.

Attitude of Mv among the participants

The Attitude-based section of the study involving 545 participants regarding the Materiovigilance Programme of India (MvPI) reveals shifts in attitudes before and after an intervention from the above Table 3. The table reflects participants' responses categorized into Strongly Agree (SA), Agree (A), Neutral (N), Disagree (D), and Strongly Disagree (SD). Across all five questions, there's a consistent pattern of increased agreement post-intervention. For instance, participants demonstrated a notable improvement in their attitudes towards Materiovigilance. Awareness that medical devices can cause adverse events increased from 52.85% to 72.9%, and the belief in the importance of reporting these events rose from 69.36% to 76.69%. The perceived necessity of training on Materiovigilance for pharmacy students also grew, with agreement increasing from 71.01% to 81.28%. Additionally, the view that reporting adverse events enhances patient safety strengthened from 74.12% to 81.11%. Willingness to report adverse events improved significantly, rising from 66.04% to 80.55%. These changes reflect a successful enhancement in participants' understanding and attitudes towards Materiovigilance, indicating that the intervention effectively increased their commitment to patient safety and the value of reporting adverse events. Therefore, the overall trends reflect a growing consensus on the significance of Materiovigilance in ensuring patient safety, and the results highlight the effectiveness of educational initiatives in shaping attitudes within the pharmacy community

Perception of Mv among the study participants

The Perception-based section of the study in the Table 4, involving 545 participants regarding the Materiovigilance Programme of India (MvPI), illustrates shifts in perceptions before (PRE) and after (POST) an intervention. The table categorizes responses into Strongly Agree (SA), Agree (A), Neutral (N), Disagree (D), and Strongly Disagree (SD). Across all five questions, there's a distinct change in perceptions as observed in post-intervention. Initially, only 56.33% (8.07% strongly agree, 48.26% agree) believed that MvPI could generate evidence-based data on medical device safety, but this increased to 76.24% (20% strongly agree, 56.24% agree). The belief that a single report of an adverse event could impact the healthcare system also grew from 52.66% (11.01% strongly agree, 41.65% agree) to 74.04% (21.1% strongly agree, 52.94% agree). Awareness of the consequences of not reporting adverse events improved, with agreement rising from 40% (7.89% strongly agree, 32.11% agree) to 70.01% (20.55% strongly agree, 50.46% agree). The perception of Materiovigilance reporting as a potential area for professional growth increased from 59.09% (10.83% strongly agree, 48.26% agree) to 78.25% (23.30% strongly agree, 54.95% agree). Additionally, the perceived need for greater awareness and understanding among pharmacy students improved from 68.63% (16.15% strongly agree, 52.48% agree) to 81.66% (26.61% strongly agree, 55.05% agree). These results indicate a positive shift in participants' perceptions, reflecting an enhanced recognition of the importance and impact of Materiovigilance. The perception results tell us about the notable increase in the belief that MvPI generates valuable safety data, that reporting adverse events impacts the healthcare system, and that reporting contributes to professional growth. Additionally, awareness of the need for greater understanding among pharmacy students was strengthened, indicating a successful enhancement in participants' recognition of the importance of Materiovigilance.

KAP of Mv among the participants

The Materiovigilance (Mv) intervention yielded significant improvements in participants' understanding, attitudes, and perceptions towards medical device safety, extracting from

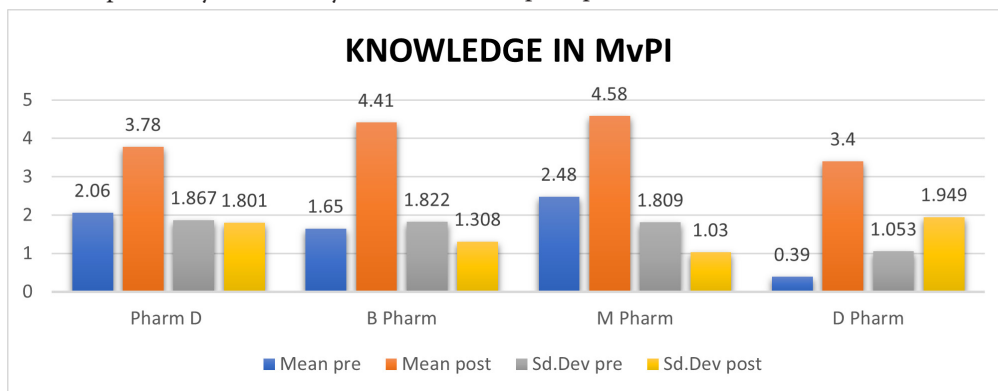


Figure 5: Knowledge of the participants.

Table 3: Attitude of Mv among the participants.

Sl. No.	Attitude Based Questions	MvPI (n=545)									
		Pre [N (%)]					Post [N (%)]				
		SA	A	N	D	SD	SA	A	N	D	SD
1	Do you agree that medical devices can cause adverse events?	51 (9.35)	236 (43.5)	184 (33.7)	34 (6.2)	40 (7.33)	117 (21.4)	281 (51.5)	69 (12.6)	25 (4.58)	53 (9.7)
2	Do you agree that it is important to report the adverse events caused by medical devices?	137 (25.14)	241 (44.22)	95 (17.43)	35 (6.42)	37 (6.79)	159 (29.17)	259 (47.52)	59 (10.83)	19 (3.49)	49 (9)
3	Do you agree that training on materiovigilance to the pharmacy students is essential?	115 (21.10)	272 (49.91)	99 (18.17)	18 (3.30)	41 (7.52)	162 (29.72)	281 (51.56)	42 (7.71)	16 (2.94)	44 (8.07)
4	Do you agree that reporting of adverse event will enhance patient safety?	136 (24.95)	268 (49.17)	78 (14.31)	18 (3.30)	45 (8.26)	168 (30.83)	274 (50.28)	46 (8.44)	16 (2.94)	41 (7.52)
5	If you come across any adverse event related to medical devices, would you report it?	101 (18.52)	259 (47.52)	117 (21.47)	28 (5.14)	40 (7.34)	148 (27.16)	291 (53.39)	50 (9.17)	14 (2.57)	42 (7.71)

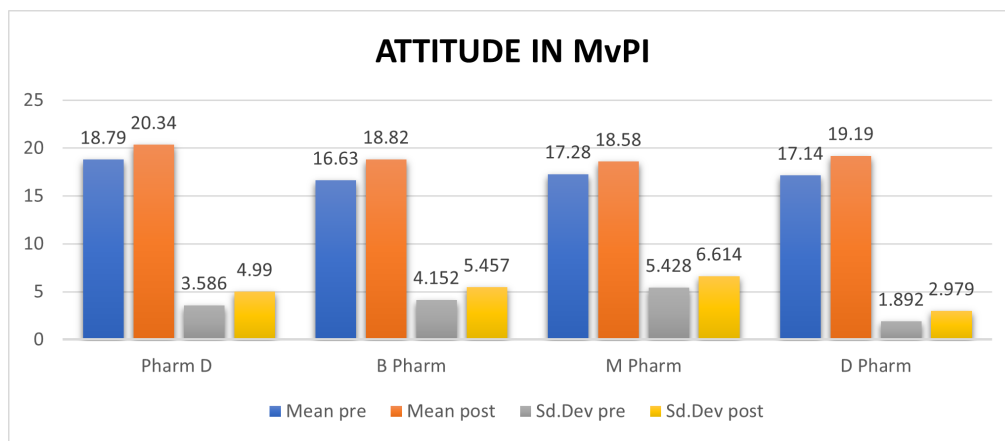


Figure 6: Attitude of the study participants.

Table 5. Following the intervention, participants demonstrated remarkable increases in their knowledge levels, with a substantial rise in correct responses to knowledge-based questions. This improvement underscores the effectiveness of the intervention in enhancing participants' comprehension of Materiovigilance Program of India (MvPI) procedures and reporting mechanisms. Moreover, the intervention positively influenced participants' attitudes towards reporting adverse events caused by medical devices, as evidenced by a higher percentage of participants

expressing agreement and strong agreement post-intervention. Similarly, participants' perceptions regarding the significance and potential impact of Mv on patient safety and healthcare systems were notably enhanced. The intervention's success was further supported by qualitative feedback, which highlighted participants' recognition of the importance and relevance of Materiovigilance training. These findings underscore the critical role of targeted educational interventions in promoting medical device safety and fostering a culture of vigilance among healthcare professionals.

Comparison of Knowledge, Attitude and Perception of Materiovigilance among the pharmacy students

Knowledge of Mv among pharmacy students

The below Table 6 presents result from a *t*-test analysis comparing pre- and post-intervention mean scores (Mv) across four classes: Pharm D, B Pharm, M Pharm, and D Pharm. Each class had a different number of participants (N). Before the intervention, the mean scores varied across classes: Pharm D had a mean of 2.06, B Pharm had a mean of 1.65, M Pharm had a mean of 2.48, and D

Pharm had a mean of 0.39. Post-intervention means scores also varied: Pharm D had a mean of 3.78, B Pharm had a mean of 4.41, M Pharm had a mean of 4.58, and D Pharm had a mean of 3.40. The standard deviation (Sd. Dev) for both pre- and post-intervention scores differed across classes as well. The *t*-test results showed exceptionally huge contrasts ($p < 0.001$) between pre- also post-intervention scores for all classes, suggesting that the intervention had a significant impact on the participants' scores across all classes following Figure 5.

Table 4: Perception of Mv among the study participants.

Sl. No.	Perception Based Questions	MvPI (545)									
		Pre [N (%)]					Post [N (%)]				
		SA	A	N	D	SD	SA	A	N	D	SD
1	Do you believe that India's materiovigilance programme can generate evidence-based data on medical device safety?	44 (8.07)	263 (48.26)	177 (32.48)	24 (4.4)	37 (6.7)	109 (20)	306 (56.24)	76 (13.94)	17 (3.12)	37 (6.79)
2	Do you think that one report of adverse event related to medical device will make any difference in health care system?	60 (11.01)	227 (41.65)	167 (30.64)	60 (11.01)	31 (5.69)	115 (21.1)	288 (52.94)	79 (4.51)	29 (5.32)	34 (6.24)
3	Are you aware of the potential consequences of not reporting adverse events related to medical devices?	43 (7.89)	175 (32.11)	265 (48.62)	30 (5.50)	32 (5.87)	112 (20.55)	275 (50.46)	113 (20.73)	19 (3.49)	26 (4.77)
4	Do you perceive Materiovigilance reporting as a potential area for your professional growth and development in the field of pharmacy?	59 (10.83)	263 (48.26)	168 (30.83)	26 (4.77)	29 (5.32)	127 (23.30)	299 (54.95)	69 (12.66)	14 (2.57)	36 (6.61)
5	Do you perceive a need for greater awareness and understanding of Materiovigilance among pharmacy students?	88 (16.15)	286 (52.48)	121 (22.20)	19 (3.49)	31 (5.69)	145 (26.61)	300 (55.05)	58 (10.64)	13 (2.39)	29 (5.32)

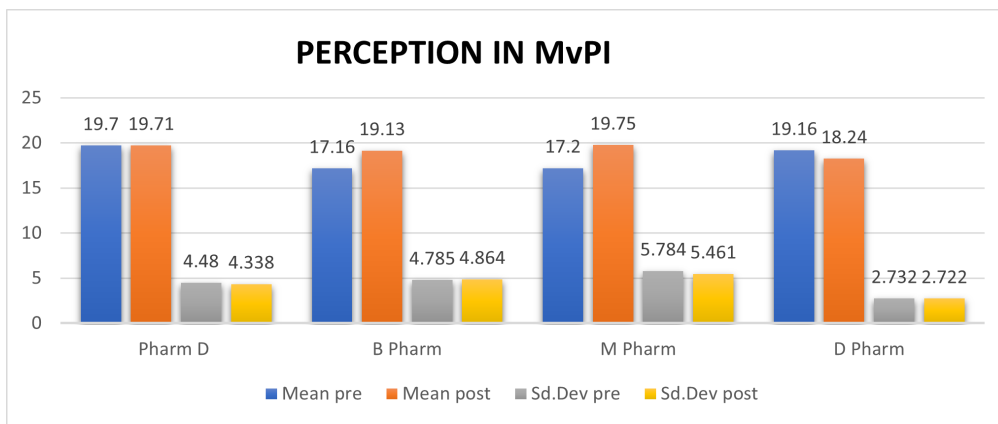


Figure 7: Perception of the participants.

Table 5: KAP of Mv among the participants.

Sl. No.	Total KAP of MvPI	MvPI (n=545)			
		Pre (%)		Post (%)	
		Correct	Incorrect	Correct	Incorrect
1	Knowledge	28.58	82.42	82.71	16.62
2	Attitude	66.63	34.3	78.52	23.99
3	Perception	55.33	44.17	76.18	23.8

Attitude of Mv among pharmacy students

The above Table 7 presents results from a t-test analysis comparing pre- and post-intervention mean scores (Mv) across four classes: Pharm D, B Pharm, M Pharm, and D Pharm. Each class had a different number of participants (N). Before the intervention, the mean scores varied across classes: Pharm D had a mean of 18.79, B Pharm had a mean of 16.63, M Pharm had a mean of 17.28, and D Pharm had a mean of 17.14. Post-intervention means scores also varied: Pharm D had a mean of 20.34, B Pharm had a mean of 18.82, M Pharm had a mean of 18.58, and D Pharm had a mean of 19.19. The standard deviation (Sd. Dev) for both pre- and post-intervention scores differed across classes as well. The t-test results shown exceptionally huge contrasts ($p < 0.001$) among pre-and post-mediation scores for Pharm D, B Pharm, and D Pharm classes, suggesting that the intervention had a significant impact on the participants' scores. However, for the M Pharm class, while there was a distinction from pre-and post-intervention scores, it wasn't important through statistic wise ($p = 0.261$) showing in Figure 6.

Perception of Mv among pharmacy students

Table 8 presents results from a t-test analysis comparing pre- and post-intervention mean scores (Mv) across four classes: Pharm D, B Pharm, M Pharm, and D Pharm. Each class had a different number of participants (N). Before the intervention, the mean scores varied across classes: Pharm D had a mean of 19.70, B Pharm had a mean of 17.16, M Pharm had a mean of 17.20, and D Pharm had a mean of 19.16. Post-intervention means scores

also varied: Pharm D had a mean of 19.71, B Pharm had a mean of 19.13, M Pharm had a mean of 19.75, and D Pharm had a mean of 18.24. The Standard Deviation (Sd. Dev) for both pre- and post-intervention scores differed across classes as well. The t-test results demonstrated a measurably huge contrast ($p < 0.001$) between pre- and post-intervention scores for B Pharm and D Pharm classes. However, for the M Pharm class, while there remained a variation of pre- also post-intervention scores, it was statistically significant only at the significance level of 0.019.

For the Pharm D class, there was no measurably massive contrast among pre-and post-mediation scores ($p = 0.987$) depicting in Figure 7.

DISCUSSION

Only 27.7% of participants in our study were aware of the MvPI, which demonstrated the understanding, beliefs, and perceptions of various pharmacy streams regarding the reporting of MDAEs and materiovigilance. 69.36% of study participants thought it was important to report these events. Finally, only 40% of participants were aware of the impacts of failing to report adverse events in a timely manner, which was in line with the findings of Manna N *et al.*'s study (2023), in which 44.93% of participants had adequate knowledge of MvPI and 10.58% stated that they disclosed of addressing only one MDAE.

In contrast to our study, Samal S. *et al.*, (2022) found that most adverse events related to medical devices were caused by devices with low-to-moderate risk (Class B) or low-risk (Class A) which led to data inaccuracy (misreading). In disparity, only 28.2%

Table 6: T-test analysis of Knowledge among Pharmacy students

Sl. No.	Class	N	Mean±Sd. Dev		p-value
			Pre	Post	
1	Pharm D	154	2.06±1.867	3.78±1.801	<0.001*
2	B Pharm	208	1.65±1.867	4.41±1.308	<0.001*
3	M Pharm	60	2.48±1.867	4.58±1.030	<0.001*
4	D Pharm	123	.39±1.867	3.40±1.949	<0.001*

*Significantly significant $p < 0.05$.

Table 7: T-test analysis of attitude among Pharmacy students (Mv).

Sl. No.	Class	N	Mean±Sd. Dev		p-value
			PRE	POST	
1	Pharm D	154	18.79±3.586	20.34±4.990	<0.001
2	B Pharm	208	16.63±4.152	18.82±5.457	<0.001
3	M Pharm	60	17.28±5.428	18.58±6.614	0.261
4	D Pharm	123	17.14±1.892	19.19±2.979	<0.001

*Significantly significant $p < 0.05$.

Table 8: T-test analysis of perception between Pharmacy students (Mv).

Sl. No.	Class	N	Mean±Sd. Dev		p-value
			PRE	POST	
1	Pharm D	154	19.70±4.480	19.71±4.338	0.987
2	B Pharm	208	17.16±4.785	19.13±4.864	<0.001*
3	M Pharm	60	17.20±5.784	19.75±5.461	0.019*
4	D Pharm	123	19.16±2.732	18.24±2.722	0.004*

*Significantly significant $p < 0.05$.

of respondents in our study were aware of the classification of medical devices.

The fact that Indushree *et al.* (Indushree *et al.*, 2023) conducted a questionnaire-based study on a KAP of Mv is another finding that is comparable to our study, where most healthcare professionals embraced awareness and prevention of MDAEs, the importance of materiovigilance, and also materials or reading articles regarding Mv and MDAEs.

Similar to the findings of our study, study participants (76.81%) agreed that Mv should be taught in depth to healthcare specialists in our healthcare service. The findings of Sivagourounadin *et al.*, (2022) study, in which 80.85% of the respondents expressed agreement with the idea that reporting MDAEs is a professional responsibility in the healthcare industry, were pretty like our study.

Regarding our study, most participants lacked knowledge, indicating a positive attitude toward MDAEs. According to another study done by Meher BR, most of them believed that reporting adverse events would improve patient safety and that a simple or complex medical device can cause adverse events if not used appropriately (Meher *et al.*, 2022).

CONCLUSION

The given study revealed a significant improvement in the Knowledge, Attitude and Perception among the pharmacy students comprising of (Pharm D, B Pharm, M Pharm, and D Pharm) towards the Materiovigilance Programme of India (MvPI) after the intervention. This study highlights that in Pre-test there was a less significant performance of all the streams and was found to be less profound and impactful. The post-test after the educational intervention resulted in a substantial increase of MvPI, understanding of medical device classification, and knowledge of reporting mechanisms. Additionally, the participants' attitudes toward the importance of reporting adverse events and the need for training showed marked optimism. Lastly, the perception of MvPI as a valuable program for patient safety, professional growth, and the need for greater awareness was found to have remarkably improved in Pharmacy students as an overall. Thus, we can conclude that the intervention was highly effective in enhancing the participants involvement and to improvise the understanding of MvPI. This study also suggests us the crucial necessity of developing a proper Materiovigilance Program in the curricula with necessary training and its implementation.

Hence, it will help in fostering professional development of all the participants of pharmacy (field) in the near future.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

B Pharm: Bachelor Of Pharmacy; **D Pharm:** Diploma Of Pharmacy; **MDAEs:** Medical Device Adverse Events; **M Pharm:** Master of Pharmacy; **MvPI:** Materiovigilance Programme of India; **KAP:** Knowledge, Attitude, and Perception; **CDSCO:** Central Drugs Standard Control Organisation; **Pharm D:** Doctor of Pharmacy; **WHO:** World Health Organization; **SA:** Strongly Agree; **A:** Agree; **N:** Not sure; **D:** Disagree; **SD:** Strongly Disagree; **Sd:** Standard Deviation; **IEC:** Institutional Ethical Committee; **IBM SPSS:** International Business Machines Statistical Package for the Social Sciences.

ETHICAL APPROVAL

Ethical clearance was obtained from the institutional ethical committee, KLE College of Pharmacy, Hubballi. IEC No. KLECOPH/IEC/2023-24/01.

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