

A Questionnaire-Based Study to assess Knowledge, Attitude, and Practice of Materiovigilance among practicing Interns in a Tertiary Care Hospital, North Karnataka

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KEYWORDS	ABSTRACT
Materiovigilance, Medical Devices Associated Adverse Events (MDAEs), Materiovigilance Programme of India (MvPI)	BACKGROUND; Materiovigilance is the study and follow up of incidents that might result from the use of medical devices. It enables to identify the adverse events associated with the use of medical devices. Ministry of Health & Family Welfare, Govt. of India approved and commenced Materiovigilance Programme of India (MvPI) in the country in order to monitor the safety of Medical Devices Associated Adverse Events (MDAEs) in Indian Population. The study aims to assess the knowledge, attitude, and practice of spontaneous reporting of Materiovigilance of Interns in a tertiary care hospital and aspires to find effective ways to encourage, educate, and equip them to improve the quality and accuracy of spontaneous medical devices associated adverse events reporting in a hospital set up. OBJECTIVES: To assess the knowledge, attitude, and practice of materiovigilance among Interns in a tertiary care hospital. MATERIALS AND METHODS: This was an observational, cross-sectional, and questionnaire-based study. Data were collected from willing participants among the practicing Interns from the tertiary care centre, Bidar using google forms. Data were entered into the Microsoft Excel sheet. The statistical analysis was carried out using Microsoft Excel 2021. Categorical data were presented as numbers and percentages, while continuous data were presented as mean $\pm$ standard deviation. RESULTS: Out of 120 participants, 63 have scored $<80\%$ and 57 have scored $>80\%$ in knowledge aspect of materiovigilance. Around 92.5% thought that MDAE reporting should be compulsory and 87.5% of participants were willing to report. But 64.2% of participants mentioned that they haven't been trained on how to report a MDAE and 63.3%

haven't seen a MDAE form. **CONCLUSION:** From this study we observe that the young doctors had adequate knowledge and positive attitude regarding materiovigilance. But the practice of reporting MDAE was lacking. Hence, sensitization of materiovigilance is necessary on a periodical basis through conferences and CMEs.

Introduction:

Globally, medical devices have an immensely important role in diagnosis, prevention, and treatment of different diseases. The World Health Organization has defined medical device as “any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of or compensation for an injury, investigation, replacement, modification, or support of the anatomy or of a physiological process, supporting or sustaining life, control of conception, disinfection of medical devices providing information by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.”(1)Recent stride in scientific innovation has substantially increased the role medical devices in the health-care delivery system. More than a million medical gadgets are available, ranging from inexpensive, basic items like tongue depressors and bandages to expensive, sophisticated ones like medical software and magnetic resonance imaging machines. Every piece of medical equipment has certain potential risks. Many times, medical devices use has caused morbidity and mortality in the device users. (2)United States Food and Drug Administration (USFDA) has classified medical devices into three categories i.e., Class-I, Class-II, and Class-III. Class-I includes devices with the lowest risk and Class-III includes those with the greatest risk (3); whereas Central Drugs Standard Control Organisation (CDSCO) has classified medical devices into four categories in 2017 as- Class A (low-risk), Class B (low moderate risk), Class C (moderate high-risk) and Class D (high-risk). (4)Recognizing the increasing importance of medical devices in the health-care delivery, the World Health Organization has recommended an essential diagnostics list like that of essential medicines list.(5)

In India, safety, quality, and performance of medical devices are regulated as per Drug and Cosmetic Acts, 1940 and Rules, 1945. India did not have a proper system to monitor the adverse events associated with uses of medical devices for a long period of time (6) To regulate the import, manufacture, sales, and distribution of medical devices, Government of India in consultation with Drugs technical advisory board has recently brought out Medical Devices Rules, 2017 (6) followed by National Medical Device Policy 2023. (7)

Materiovigilance refers to close monitoring of any undesirable occurrences resulting from the use of medical devices by means of having a system in place which comprises identifying, collecting, reporting, and estimating undesirable occurrences and reacting to them, or safety corrective actions after their post marketing phase (8,9)

The Materiovigilance Program of India (MvPI) was launched on July 6, 2015, by Drug Controller General of India Dr. G.N. Singh at Indian Pharmacopoeia Commission, Ghaziabad to raise awareness among health-care providers about the need for reporting medical device-associated adverse events and to provide independent, reliable, and evidence-based medical device safety data. (10)The fundamental aim of this program is to monitor medical device-associated adverse events(MDAE), create awareness among health-care professionals about the importance of MDAE reporting and generate independent credible evidence-based safety data of medical devices and to share it with the stakeholders.[10]

Most common and risky medical devices have led to negative consequences include breast implants, pacemakers, contraceptives, incubators, and artificial hips grafted into patients' bodies. An international inquiry revealed that despite being deemed hazardous, a number of medical gadgets were still being supplied in international markets [11]. More than 1.7 million reported injuries and more than 83,000 reported deaths globally due to the usage of such dangerous medical equipment have been documented over the course of the last 12 years [11].

Despite the fact, the program has been started 9 years ago, we found only few studies regarding the awareness, knowledge, attitude, and practice of medical professionals toward materiovigilance and factors influencing underreporting. Poor knowledge, attitude, and practice of MDAE reporting was also observed among Healthcare Professionals in studies carried out in other countries. [12,13,14] Interns being exposed to all the clinical departments and seeing the adverse reactions due to the medical device should have enough knowledge, good attitude, and practice of identifying and reporting such events.Hence, the present study was carried out to assess Knowledge, Attitude, Practice of materiovigilance among Interns in a tertiary care teaching hospital in northKarnataka.

Materials and Methods:

This was an observational, cross-sectional, questionnaire-based study conducted in Department of Pharmacology in a tertiary care teaching hospital of north Karnataka. The study was conducted for three monthsfrom October 2023 to December 2023 among practicing interns.The study was initiated after getting approval from Institutional Ethics committee with letter no. 233/BRIMS/IEC/2023 dated 10/10/2023.

Participation in the study was voluntary. The practicinginterns were briefed about the rationale of the study and participants were assured of the privacy and confidentiality of data. The informed consent to take part in the study was also taken before enrolling them in the study.

Other health care workers were excluded from the study.

Study Procedure:

A structured self-administered Google form-based questionnaire in the English language was prepared to collect the relevant data of the study variables. The questionnaire contained a total of 18 questions related to Knowledge, Attitude, Practice aspects of the materiovigilance in three sections. The questionnaire was validated with content validity index. (15) For this, a panel of six peer experts reviewed each question individually and Content Validity Index (CVI) was calculated, which obtained a score of 0.83. The questionnaire was then distributed to the study participants through a digital web link using Google forms.

Link was provided to the participants and responses received within 30 minutes was considered for analysis. For logistics reasons, if the participant is not equipped to fill in the digital form, a physical form containing the same set of questions was given to the participant and the written response was collected within 30 minutes. There was a total of seven multiple-choice questions related to the knowledge aspect of materiovigilance. Knowledge of the study participants was assessed using a scoring system, where we gave a score of “1” for each correct answer and a score of “0” for each incorrect answer. Moreover, there was a total of 11 questions related to attitude, and practice aspect of materiovigilance (six questions on attitude and five questions on practice domain). Out of those 11 questions, nine were closed-ended and participants have to select the response from “YES” or “NO,” two questions were with 4-point Likert scale with choices of “Strongly agree,” “Agree,” “Disagree,” and “Strongly disagree.

Statistical analysis:

Data were entered into the Microsoft Excel sheet. The statistical analysis was carried out using Microsoft Excel 2021. Categorical data were presented as numbers and percentages, while continuous data were presented as mean $\pm$ standard deviation.

Results:

We got a total of 120 responses during the study period. The majority of participants belonged to the age group of 23-25 years (n=62, 51.7%) and <23 years (n= 57, 47.5%) (Figure 1). Out of 120 participants 63(52.5%) participants were male, 53 (44.2%) participants were female and 4(3.3%) preferred not to reveal their gender. (Table-1, Figure-2)

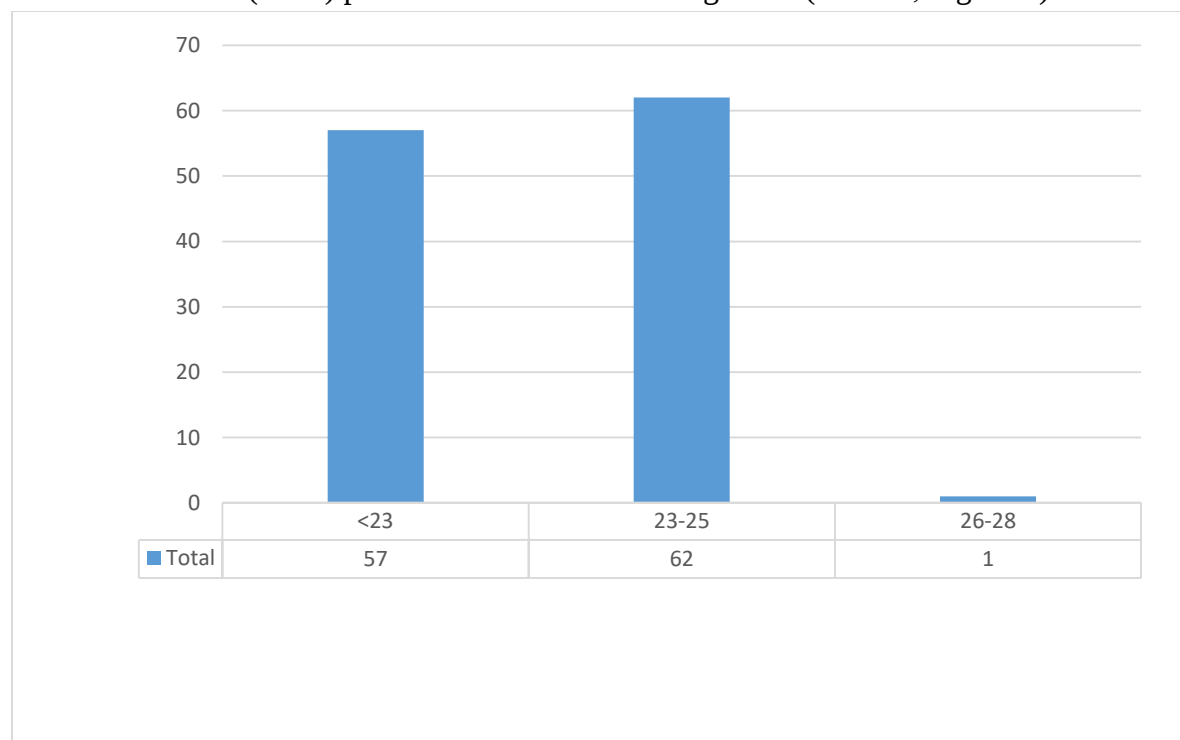


Figure 1: Count of Age

Table 1: Demographic characteristics of study participants (n=120)

Demographic characteristics	Categories	Frequency
Age		
	<23 years	57 (47.5%)
	23-25 years	62 (51.7%)
	26-28 years	1 (0.8%)
Gender		
	Male	63 (52.5%)
	Female	53 (44.2%)
	Prefer not to say	4 (3.3%)

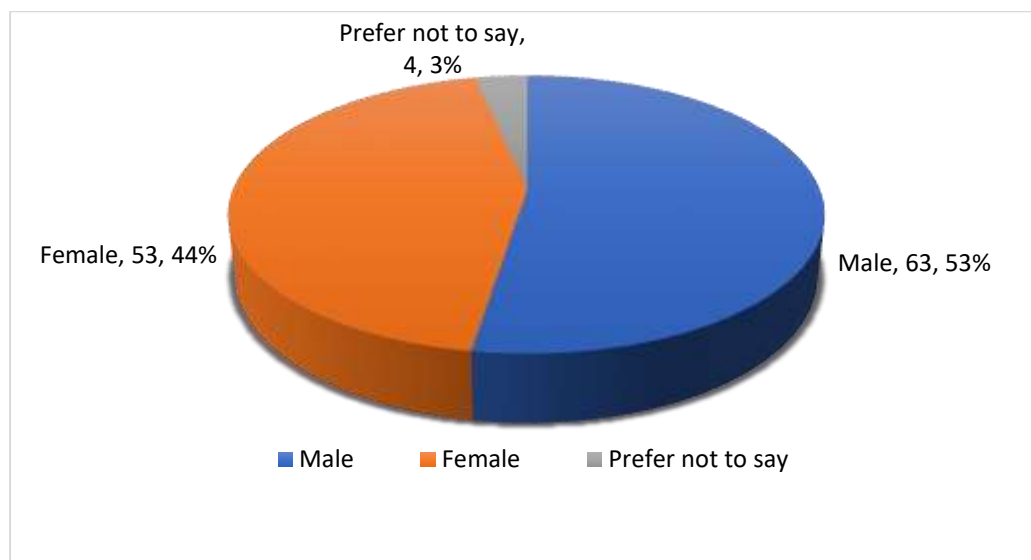


Figure 2: Gender:Male/Female Ratio

Assessment of Knowledge:

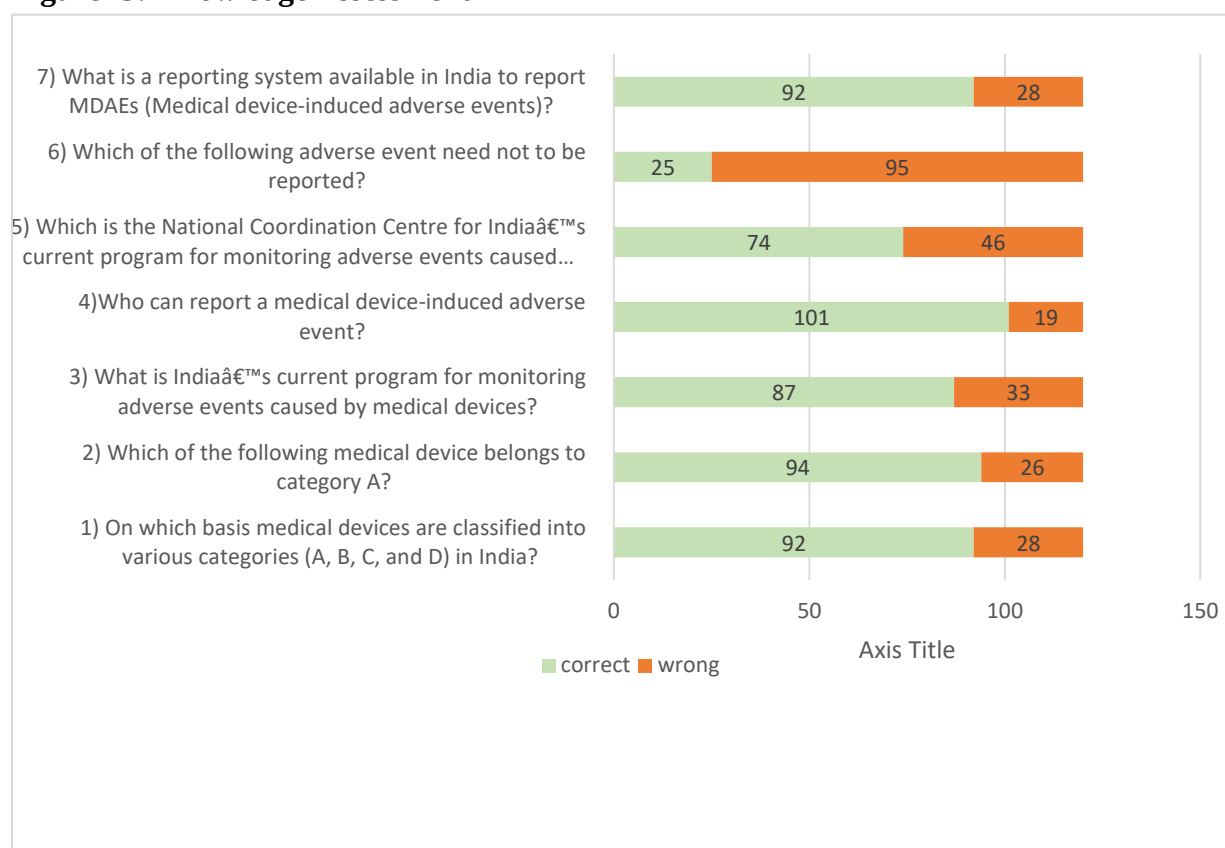
There were total of seven questions in the questionnaire to assess the knowledge aspect of materiovigilance. The mean score of each participant is 4.3 ± 1.6 . Out of 120 participants, 57 have scored $>80\%$ and 63 have scored $<80\%$. Almost 76.7% (92) of participants gave correct answers related to classification of medical devices. 72.5% (87) of participants were aware of India's vigilance program for medical devices, 61.7% (74) of them knew its national coordinating centre, and 76.7% (92) of them knew the reporting system available in India to report MDAE. But only 20.8% (25) of the participants knew which MDAE need not to be reported. (Table 2, Figure -3)

Table- 2: Knowledge of materiovigilance among study participants

Section 1: Knowledge	Correct response n (%)	Incorrect response n (%)
1) On which basis medical devices are classified into various categories (A, B, C, and D) in India? (a) Based on the risk they carry while their use* (b) Based on their price (c) Based on the condition (s)/disease (s) for which they are being used (d) Based on their complexity of structure	92 (76.7%)	28 (23.3%)
2) Which of the following medical device belongs to category A? (a) Cardiac pacemaker (b) Bandage* (c) MRI Machine (d) Orthopedic implant	94 (78.3%)	26 (21.1%)
3) What is India's current program for monitoring adverse events caused by medical devices? (a) Medical devices safety program of India (b) Medical devices single audit program of India (c) Materiovigilance program of India (d) Pharmacovigilance program of India	87 (72.5%)	33 (27.5%)
4) Who can report a medical device-induced adverse event? (a) Doctors only (b) Nurses (c) Medical device manufacturer (d) All of the above	101 (84.2%)	19 (15.8%)
5) Which is the National Coordination Centre for India's current program for monitoring adverse events caused by medical devices? (a) Indian pharmacopeia commission (b) Central drugs standard control organization (c) All India institute of medical science, New Delhi (d) PGIMER, Chandigarh.	74 (61.7%)	46 (38.3%)
6) Which of the following adverse event need not to be reported? (a) Surgical gloves causing irritation of the skin (b) Death of patient due to fire in the incubator (c) Infusion pump fails to give an appropriate alarm (d) None of the above	25 (20.8%)	95 (79.2%)

7) What is a reporting system available in India to report MDAEs (Medical device-induced adverse events)? (a) By toll-free helpline number 1800 180 3024 (b) By Medical Device Adverse Event (MDAE) reporting form (c) By MDAE Reporting Application (d) All of the above	92 (76.7%)	28 (28.3%)
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Figure- 3: Knowledge Assessment



Assessment of Attitude:

There were six questions to assess attitude of participants towards materiovigilance. 95.9% (115) of participants agree that medical devices can cause adverse event. 92.5% (111) of participants thought that reporting is compulsory. 87.5% (105) of participants were willing to report MDAE and 90% (108) of participants agree that it was a medical professional's responsibility. 97.5% (117) of participants agreed that reporting MDAE's will improve patient safety. 91.7% (110) of participants said that materiovigilance should be taught in detail to medical professionals. (Table -3)

Table- 3: Attitude towards materiovigilance among study participants

Section 2: Attitude	Response	n (%)
8) Do you agree medical devices can cause an adverse event?		
	(a) Strongly agree	38 (31.7%)
	(b) Agree	77 (64.2%)
	(c) Disagree	4 (3.3%)

	(d)Stronglydisagree	1 (0.8%)
9) Do you think it is a medical professional's responsibility to report every medical device-induced adverse event?	Yes	108 (90%)
	No	12 (10%)
10) Do you think medical device-induced adverse event reporting should be compulsory?	Yes	111 (92.5%)
	No	9 (7.5%)
11) Do you agree that reporting medical device-induced adverse events can improve patient safety and so must be encouraged?	(a)Strongly agree	56 (46.7%)
	(b) Agree	61 (50.8%)
	(c)Disagree	1 (0.8%)
	(d)Strongly disagree	2 (1.7%)
12) Are you willing to report a medical device-induced adverse event?	Yes	105 (87.5%)
	No	15 (12.5%)
13) Should materiovigilance be taught in detail to medical professionals?	Yes	110 (91.7%)
	No	10 (8.3%)

Assessment of Practice

There was a total of six questions in the questionnaire to assess the practice of study participants regarding materiovigilance. 76.7% (92) of participants take feedback from patients after implanting the device. 35% (42) of participants have experienced a MDAE during their clinical practice in general but only 18.3% (22) of them reported MDAE during their practice. Also 64.2%(77) of participants responded that they haven't been trained on hoe to report a medical device induced adverse event and 63.3%(76) of participants responded that they haven't seen the Medical device induced adverse event reporting form. (Table-4)

Table- 4:Practice of materiovigilance among study participants

Section 3: Practice	Response	n (%)
14)Have you ever experienced an adverse event because of medical device use in any patient during your practice?	Yes	42 (35%)
	No	78 (65%)
15)Have you ever reported medical device-induced adverse events during your practice?	Yes	22 (18.3%)
	No	98 (81.7%)

16)Have you ever been trained on how to report a medical device-induced adverse event?	Yes	43 (35.8%)
	No	77 (64.2%)
17)Have you seen the medical device adverse event reporting form?	Yes	44 (36.7%)
	No	76 (63.3%)
18) Do you take any feedback for any untoward events from patients after implanting the device?	Yes	92 (76.7%)
	No	28 (23.3%)

Discussion:

It is widely acknowledged that ensuring the safety and high quality of medical devices requires an active, well-organized surveillance system. In addition, each of these actions has the

potential to improve patient safety and the healthcare system.(13,16,17) One of the primary goals of MvPI is to raise awareness among stakeholders on the value of MDAE reporting [18]. There are several KAP studies on pharmacovigilance performed among medical personnels, however, there are relatively fewer KAP surveys conducted on materiovigilance [19]. The present study is one such attempt to raise awareness and analyse the current scenario on the case.

In our study we found that Knowledge regarding materiovigilance was satisfactory (mean score 4.3 ± 1.6) yet insufficient because 52.5% (n= 63) have scored less than 80%(Figure -4) which was better when compared to study conducted by Panchal et al (20). In this present study, 76.7% (n=92) of participants were aware of categories of medical devices where as in a study conducted by Panchal et al, it was only 56.4% and in a study conducted by Modi K et al(21) it was 35.6%. But in study conducted by Meher et al(13), 88.6% were aware of categories of medical devices which is little higher than our study. As per present study report, 72.5%(n=87) knew about similar to study done by Modi K et al (74.6%) whereas in study done by Panchal et al and Meher et al it was relatively less (31.4% and 30.1% respectively). 61.7% (n=74) of participants knew the national coordinating center for MVPI as compared to a study conducted by Panchal et al which was 19.2%. Also 20.8% (n= 25) of participants knew what type of MDAE should not be reported which is relatively less when compared to study conducted by Panchal et al(44.9%), Mirel et al (43%), Meher et al (35%) but better when compared with Modi K et al. This shows that the participants should be trained on MDAE reporting.



Figure 4 : Knowledge- Average scores

As it is said that knowledge is of useless until it is kept in practice. So, when we talk about practice items among participants, 35% (n=42) of them have experienced an adverse event related to medical device during their practice, but only 18.3% (n=22) had reported those events during their practice (Figure -7) which was similar to study done by Panchal et al (9%) and Meher et al (19%) but relatively less when compared to study conducted by Modi K et al (45.40%). We think that some reasons for this underreporting include a busy schedule, trouble identifying the adverse event, trouble completing the causality evaluation of the adverse event, apathy toward reporting, a lack of incentives and many more. In our study, 64.2% (n=77) of participants responded that they have not been trained on how to report a MDAE which was similar to studies conducted by Panchal et al (89.7%), Meher et al (63.4%) and Sivagourounadin et al (95.2%). Also only 36.7%(44) of participants responded that they have seen a MDAE form which was better when compared to studies conducted by Panchal et al (12.8%) and Meher et al (17.5%) yet the fact that 63.3% (n=76) of participants have never seen a MDAE form was unacceptable. This can be enhanced by increasing their understanding of materiovigilance through a variety of training programs such as webinars, workshops, and Continuous Medical Education. Thus, the importance of medical device-induced adverse event reporting should be emphasized while teaching undergraduate and postgraduate students. Additionally, a few facets of the pharmacovigilance program may be implemented to enhance the materiovigilance program. The only positive aspect of this study was 76.7% (n=92) of participants responded that they take feedback from patients after implanting the device.

Despite insufficient awareness and practice, the participants of our study had an optimistic attitude towards materiovigilance. The majority of participants in our study agreed that Adverse events can occur with a medical device and reporting should be a HCP's responsibility. It was also observed that 92.5% (n=111) of participants thought reporting is compulsory (Figure-6) and 97.5% (117) responded that reporting of MDAE will improve patient's safety. 87.5% (n= 105) of participants showed their willing to report and 91.7%(n=110) responded that materiovigilance should be taught to medical professionals in

detail (Figure-5). Similar results of positive attitude were observed in participants of Panchal et al, Sivagourounadin K et al., Meher BR et al, and Modi K et al.,Whereas Gagliardi AR et al., mentioned that medical personnels had a contrary attitude and believed that reporting MDAE related to medical equipments was unnecessary and meaningless. Additionally, they did not see it, as their duty to report these events [22].

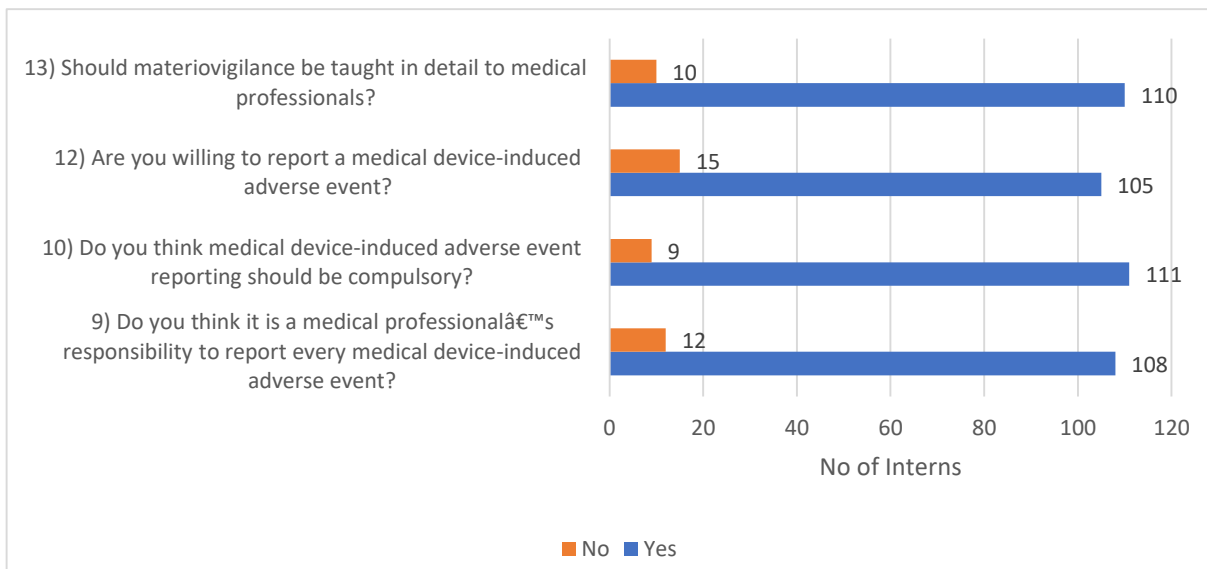


Figure- 5: Attitude Assessment

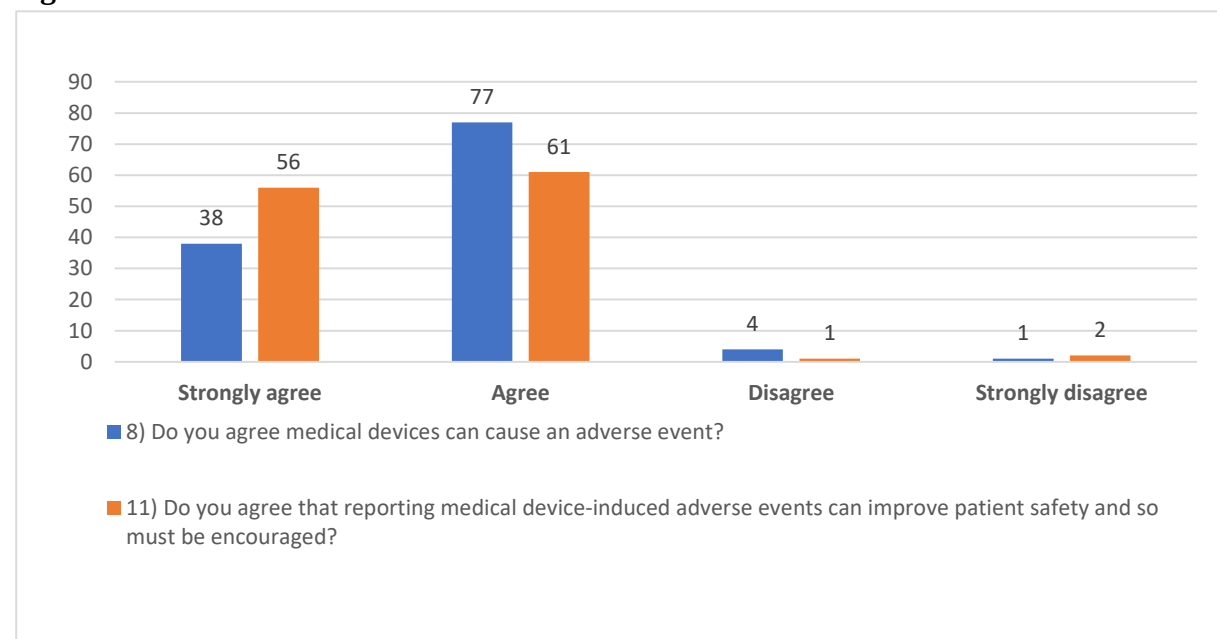


Figure-6: Attitude Assessment

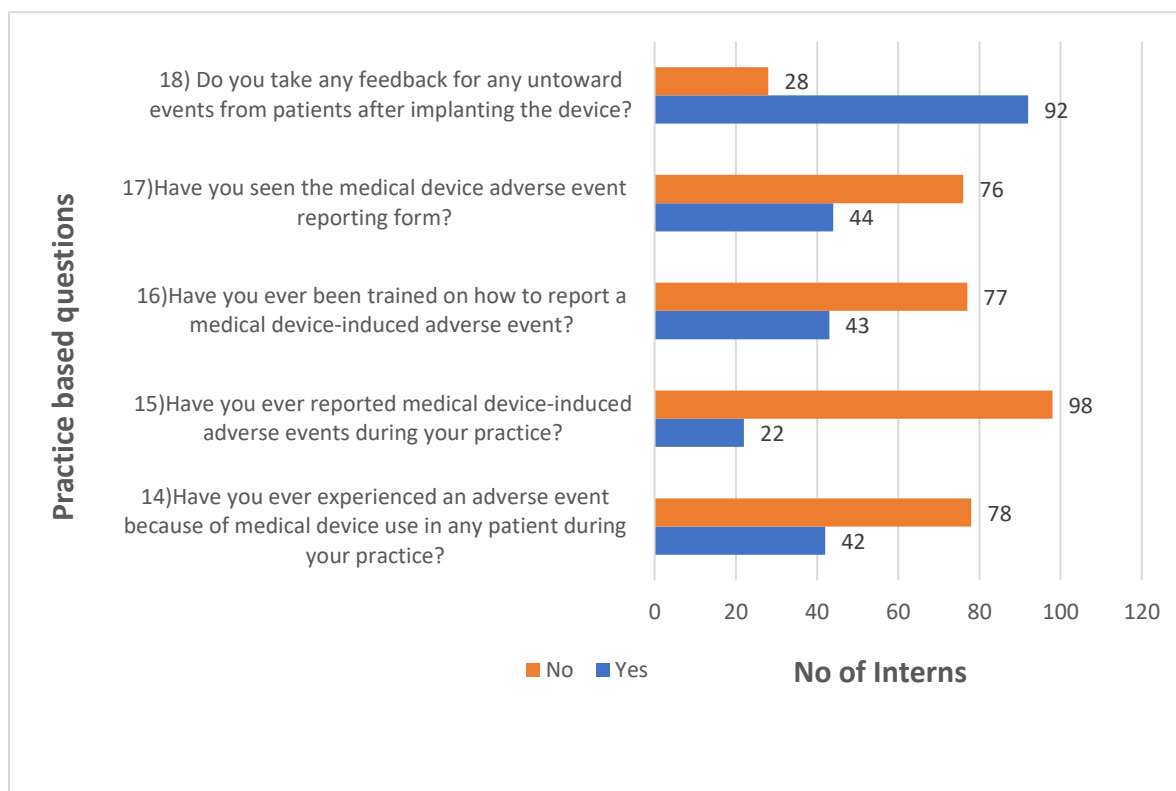


Figure 7: Practice Assessment

Limitations:

These results reflect among the practising interns of a single tertiary care centre. It would have been more considerate if the data had come from practicing doctors, nurses, and other medical professionals who oversee materiovigilance. The credibility of the data would have increased with more comparison groups. Even though our study was limited to one location, multicentric research would produce more accurate data.

Conclusion:

To Conclude, this study we conducted on young doctors of our institute emphasizes that they had adequate knowledge and positive attitude towards the necessity and compulsion of reporting MDAE to enhance patient's safety. Yet when it comes to practicing of MDAE reporting was lacking due to inadequate training sessions. Hence, sensitization of materiovigilance on a periodical basis through conferences and CMEs would be helpful in improving their knowledge and also motivate them to spontaneously report MDAE. Furthermore, materiovigilance in undergraduate medical curriculum, similar to pharmacovigilance is required to raise awareness about the rational usage of medical devices.

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Conflict of interest: None

Contribution:

Dr Sathiyathan. T, Contribution: Concepts, Design, Definition of intellectual content, Literature search, Clinical studies, Data acquisition, Data analysis, Statistical analysis, Manuscript preparation, editing and review.

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Dr Preeti Dharapur, Statistical analysis, Manuscript editing and review,

Dr. Savitha A, Concepts, Manuscript preparation, editing and review.

Dr Pramod Kulkarni, Concepts, Manuscript preparation, editing and review.

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