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Original Article

Pharmacology Section

Evaluation of Awareness, Attitude, Practice and Barriers of Adverse Events Associated with Medical Devices among Medical Doctors of Gujarat, India: A Cross-sectional Study

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ABSTRACT

Introduction: In this era of technology, the use of medical devices for betterment of patients is rapidly rising. Along with the usage, adverse events also tend to occur more with these devices. Materiovigilance Program of India (MvPI) refers to close observation of medical device-related adverse events by a well-coordinated surveillance system of detection, collection, assessment, reporting, and prevention of those events.

Aim: To evaluate the awareness, attitude, practice and barriers of adverse events associated with medical devices among doctors.

Materials and Methods: A cross-sectional study was as the study was conducted all over Gujarat, India, among 174 doctors which included medical consultants, resident doctors and intern doctors for a duration of two months from 5th November 2022 to 5th January 2023. The questionnaire was administered containing 26 questions related to awareness, attitude, practice and barriers of materiovigilance. The responses were collected via social media platform. Analysis was done in percentages and numbers and using Statistical Package for the Social Sciences (SPSS) software, version 26.0. The p-value <0.05 was considered as statistically significant.

Results: Out of 174 responders, 106 (60.9%) were males, while 68 (39.1%) were females. Mean age in present study was 27±5.3 years. There were 54 consultants, 61 residents and 59 interns. Most of the participants (98.27%) were having positive attitude, whereas, 72.98% participants had knowledge about materiovigilance and 63.21% participants have reported adverse events related to devices. Overall Knowledge, Attitude and Practice (KAP) of resident doctors was better, as compared to consultants and interns in the present study.

Conclusion: Even though there was inadequate awareness and practice, optimism in attitude was found in participants. There is a need to conduct regular workshops and training sessions for doctors to make reporting feasible and easy to reduce mishaps due to medical devices in future.

Keywords: Healthcare personnel, Knowledge, Materiovigilance, Medical equipments

INTRODUCTION

According to the Oxford dictionary, "Vigilance" is the act or state of keeping a close eye out for potential threats or problems. There is some danger associated with any medical equipment. Materiovigilance refers to the close observation of any unfavorable changes in a medical device's performance or characteristics. This is done using a system that can detect, gather, report, and estimate unfavorable occurrences and respond to them with field safety corrective actions or device recalls, during the postmarketing phase of a medical device [1].

The Materiovigilance Program of India (MvPI) was introduced by Drug Controller General of India, Dr. G.N. Singh at Indian Pharmacopoeia Commission, Ghaziabad, Uttar Pradesh, India, on July 6, 2015 to educate healthcare professionals, about the significance of reporting adverse events connected to medical devices and to offer independent, trustworthy, and evidence-based data on medical equipment safety [2].

A medical device can vary from a simple adhesive bandage or thermometer to a ventilator or a specialised diagnostic tool like a Magnetic Resonance Imaging (MRI) machine. In today's surgical, medicinal, and community healthcare setting, medical devices are frequently used. Medical device use carries a number of dangers, including incorrect use methods, numerous contraindications, device failures, and decreased device efficacy. Additionally, it has caused significant morbidity and mortality among device users [3]. 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 [4]; 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) [5].

Most common and risky medical devices that have led to negative consequences include breast implants, pacemakers, contraceptives, incubators, and artificial hips grafted into patients' bodies [6]. The 21st century saw the limelight falling on numerous case reports published on adverse event occurrences, due to medical devices failure or mishap [7-9]. An international inquiry revealed that despite being deemed hazardous, a number of medical gadgets were still being supplied in international markets [6]. 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 [6]. A total of 1931 adverse events were reported from July 2015 to October 2019 in India. Some reported hazardous events included death of 24 infants in Murshidabad Government Hospital, ventilator blast inside the Intensive Care Unit (ICU), chaos due to faulty infrared readings [10].

Although the program has been around for about six years, only few studies are published highlighting this issue [3,11,12]. Hence, present study was conducted to evaluate the awareness, attitude, practice and barriers of materiovigilance among doctors of Gujarat.

MATERIALS AND METHODS

This cross-sectional study was as the study was conducted all over Gujarat, India, over a period of two months, from 5th November 2022 to 5th January 2023. Study was processed after getting Institutional Ethical approval taken from "Sangini Hospital Ethics Committee" dated 20th October 2022.

Inclusion criteria: All medical consultants, engaged in private practice and the Government sector, medical residents and medical interns willing to participate in the study were included.

Exclusion criteria: Those who were not willing to give consent to fill the questionnaire, were excluded.

Sample size calculation: For sample size calculation, considering sample proportion=0.7298 based on pilot study and assuming population proportion=0.63. Power (1-β)%=80%, α error (%)=5%, sample size was calculated using software nMaster 2.0 was 175.

Study Procedure

A predesigned, Google form questionnaire, in English language, was created by the researchers after reviewing the literature [11,12]. It was validated by performing pilot testing in 20 participants. The reliability of the questionnaire was assessed by Cronbach's alfa (α=0.74) and was found to be reliable. Then questionnaire was sent to participants (medical consultants, resident doctors and intern doctors) using WhatsApp social media platform. In first section of questionnaire, demographic details (age, gender and designation) were collected. In second section, the study participants were briefed about the objective of study and consent was taken before initiating the questionnaire. Participants who gave consent in section two could proceed to section three, containing 26 questions.

Questionnaire included 10 questions on awareness, six on attitude, six on practice and four on barriers. Awareness was evaluated by multiple choice questions. Attitude and practice were evaluated by the close ended (Yes/No) questions. Barriers were evaluated with 5-point Likert scale. For simplifying the statistical analysis, we have categorised five-point category into neutral, agree and disagree. Median Awareness score was considered to categorise Participants overall awareness. Out of 10 questions regarding awareness, in each participant giving correct response to >5 questions was considered having "sufficient" awareness. Similarly, positive response in attitude and practice sections in >3 questions (out of six questions per section), was considered having "positive" attitude and "good practice of reporting" respectively.

Participants' responses related to awareness, attitude, practice and barriers regarding medical devices induced adverse events were collected and kept confidential.

STATISTICAL ANALYSIS

Results were expressed in percentages and numbers and analysis was done using SPSS software, version 26.0. The correct responses for each question among the three subgroups of doctors were compared using the Chi-square test. The p-value<0.05 was considered statistically significant. Median score was used to categorise the variables.

Demographic details of study participants	Frequency (n)	Percentage (%)
Age (in years)		
<25	96	55.17
26-30	34	19.54
31-35	24	13.79
>35	20	11.49
Gender		
Male	106	60.9
Female	68	39.1%
Designation		
Medical consultant	54	31.03
Resident doctor	61	35.05
Intern doctor	59	33.90

[Table/Fig-1]: Demographic details of study participants (N=174).

RESULTS

Out of 174 responders, 106 (60.9%) were males, while 68 (39.1%) were females with mean age 27±5.3 years. In present study, majority 61 (35.05%) were resident doctors, followed by the 59 (33.90%) intern doctors and 54 (31.03%) medical consultant [Table/Fig-1].

A total of 142 (81.60%) participants were aware of the current program for monitoring Medical Device-associated Adverse Events (MDAE). Number of participants who were aware of four categories of medical devices were only 79 (44.40%). A higher number of residents 53 (86.9%) were having an idea of the objectives of MvPI, as compared to the other two groups. A total of 140 (80.45%) participants knew, who can report the adverse event due to a medical device. Various ways to report adverse events were well-known by all three groups [Table/Fig-2].

In present study, 162 (93.10%) participants believed that medical devices can cause adverse events. A total of 166 (95.40%) participants agreed to the point that creating awareness about MvPI can be beneficial to patient, as well as, healthcare facilities on long term. Out of six items under attitude dimension, for one item, regarding it should be a professional obligation to report adverse outcome related with the medical devices, there was significant difference in the response by three subgroups (p=0.001) [Table/Fig-3].

Question no.	Question	"Yes" response by				
		Total n (%)	Consultants n=54, N (%)	Residents n=61, N (%)	Interns n=59, N (%)	p-value
1	The current programme for monitoring of adverse events associated with medical devices is known as?	142 (81.60)	40 (74.1)	58 (95.1)	44 (74.6)	0.37
2	When was MvPI launched?	78 (44.82)	20 (37)	37 (60.7)	21 (35.6)	0.002
3	Which is the national regulatory authority of materiovigilance?	115 (66.09)	39 (72.2)	40 (65.6)	36 (61)	0.055
4	CDSCO has classified medical devices in how many categories according to risk?	79 (44.40)	24 (44.4)	34 (55.7)	21 (35.6)	0.046
5	Which of the following constitutes the objectives of MvPI?	127 (72.98)	38 (70.4)	53 (86.9)	36 (61)	0.003
6	Who can report the adverse event due to medical device?	140 (80.45)	42 (77.8)	57 (93.4)	41 (69.5)	0.032
7	Which of the following you consider as a MDAE to be reported?	50 (28.73)	27 (50)	17 (27.9)	6 (10.2)	0.001
8	What are the ways to report MDAE?	143 (82.18)	43 (79.6)	52 (85.2)	48 (81.4)	0.942
9	Serious MDAEs should be reported within how many days?	61 (35.05)	17 (31.5)	25 (45.9)	19 (32.2)	0.046
10	How many MDMC centres are there in your state?	26 (14.94)	5 (9.3)	11 (18)	10 (16.9)	0.223

[Table/Fig-2]: Responses of questions regarding awareness (frequency and percentage).
(p-value <0.05 is statistically significant calculated by Chi-square test).

Only 80 (45.97%) doctors have ever experienced any adverse event due to medical device and only 79 (45.40%) doctors report such MDAEs in their workplaces. Only 64 (36.78%) doctors have ever attended any training of reporting MDAE whereas 164 (94.25%) of them were willing to report it in future. A total of 83 (48.27%) of doctors revealed that, they have ever been a part of learning proper usage of any medical devices [Table/Fig-4].

A total of 125 (71.83%) doctors had time constraints due to which they were not reporting MDAE and 118 (67.81%) of them mentioned that the main hindrance was non availability of offline reporting forms in their workplace. A large proportion of doctors felt that ignorance of MDAE reporting is occurring because they are not trained properly about it. A total of 114 (65.51%) participants felt that lack of remuneration is one of the reasons for lack of reporting [Table/Fig-5].

In present study, 72.98% participants scored >5 out of 10 which was considered as having "sufficient" awareness. A total of 98.27% of responders have "positive" attitude. In present study, 63.21% of responders have "good practice of reporting" [Table/Fig-6].

DISCUSSION

Worldwide, it is acknowledged that a well-organised, active surveillance system for medical devices is essential to promoting both their quality and safe use. Additionally, all of these actions have the potential to enhance the healthcare system and patient safety [13-15]. One of the primary goals of MvPI is to raise awareness among stakeholders on the value of MDAE reporting [11]. There are several KAP studies on pharmacovigilance performed among medical personnels, however, there are relatively fewer KAP surveys conducted on materiovigilance [16]. The present study is one such attempt to create awareness and analyse the current scenario on the case. Responders of this study had confined knowledge on materiovigilance. As per the present study report, majority of them knew somewhat about the programme (81.60%) which is similar to the study done by Sivagourounadin K et al., (83.5%), whereas, in study done by Panchal YN et al., and Meher BR et al., a relatively lesser percentage (35.2% and 30.1%, respectively) of responders knew about the name of the programme [11,3,12]. Only 66.09% were knowing about the National Regulatory Authority

Question no.	Question	"Yes" response by				
		Total n (%)	Consultants n=54, n (%)	Residents n=61, n (%)	Interns n=59, n (%)	p-value
11	In your opinion can medical device cause adverse event?	162 (93.10)	50 (92.6)	60 (98.4)	52 (88.1)	0.086
12	Should it be mandatory to report adverse event associated with medical device?	163 (93.67)	45 (83.3)	59 (96.7)	59 (100)	0.001
13	Is it necessary to teach how to report MDAE to undergraduate students and medical staff?	167 (95.97)	52 (96.3)	58 (94.9)	57 (96.7)	0.872
14	Do you think creating awareness about MvPI can be beneficial to patient as well as healthcare facilities on long term?	166 (95.40)	51 (94.4)	55 (91.5)	59 (100)	0.079
15	Do you think it is your moral duty to report adverse event occurring with medical devices?	164 (94.25)	52 (96.3)	58 (95.1)	54 (91.5)	0.521
16	Should there be an establishment of MDMC Centre in your institute?	149 (86.20)	48 (88.9)	48 (79.7)	53 (90.2)	0.196

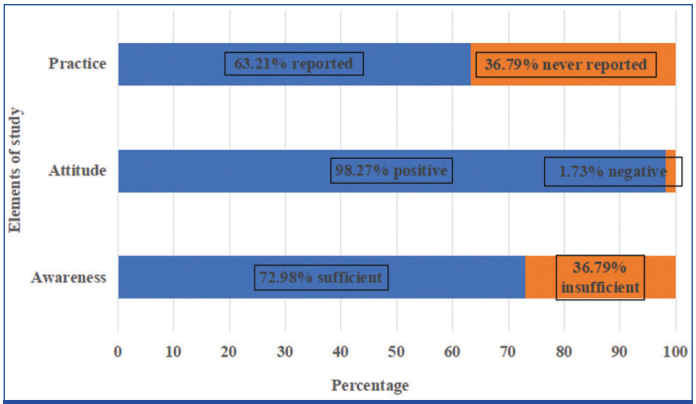
[Table/Fig-3]: Responses of Questions regarding Attitude (Frequency and Percentage).
(p-value <0.05 is statistically significant calculated by Chi-square test)

Question no.	Question	"YES" response by				
		Total n (%)	Consultants n=54, n (%)	Residents n=61, n (%)	Interns n=59, n (%)	p-value
17	Have you read any article on materiovigilance?	95 (54.59)	32 (59.3)	38 (62.3)	25 (42.4)	0.064
18	Have you experienced occurrence of MDAE during ward posting or professional practice?	80 (45.97)	27 (50)	25 (41)	28 (47.5)	0.602
19	Do you report any MDAE yourself or inform the senior doctor regarding the same?	79 (45.40)	22 (40.7)	29 (47.5)	28 (47.5)	0.709
20	Have you ever attended any workshop/CME/training organised on materiovigilance programme?	64 (36.78)	19 (35.2)	30 (49.2)	15 (25.4)	0.025
21	Are you willing to report further MDAE in future that you encounter?	164 (94.25)	52 (96.3)	58 (95.1)	54 (91.5)	0.521
22	Have you ever been a part of discussion on proper usage of any medical device and learnt what improper handling can lead to?	83 (48.27)	23 (42.6)	29 (49.2)	31 (52.5)	0.564

[Table/Fig-4]: Responses of Questions regarding Practice (Frequency and Percentage)
(p-value <0.05 is statistically significant calculated by Chi-square test). CME-Continuing medical education

Question no.	Question	Total N (%) of Agree	Response	Consultants n=54, n (%)	Residents n=61, n (%)	Interns n=59, n (%)	p-value
23	Time constraint is one of the main reasons for lack of MDAE reporting.	125 (71.83)	Agree	39 (72.2)	43 (70.5)	43 (72.9)	0.99
			Neutral	11 (20.4)	12 (19.7)	11 (18.6)	
			Disagree	4 ((7.4)	6 (9.83)	5 (8.47)	
24	Non availability of offline Materiovigilance reporting forms contributes to lack of reporting.	118 (67.81)	Agree	43 (79.6)	39 (63.9)	36 (61)	0.185
			Neutral	5 (9.3)	11 (18)	17 (28.8)	
			Disagree	6 (11.11)	11 (18.03)	6 (10.16)	
25	Lack of training leads to ignorance of reporting an event.	161 (92.52)	Agree	52 (96.3)	57 (93.4)	52 (88.2)	0.113
			Neutral	2 (3.7)	1 (1.6)	7 (11.9)	
			Disagree	0	3 (4.91)	0	
26	Lack of remuneration is one of the reasons for lack of reporting.	114 (65.51)	Agree	37 (68.5)	42 (68.9)	35 (59.3)	0.434
			Neutral	12 (22.2)	13 (21.3)	16 (27.1)	
			Disagree	5 (9.3)	6 (9.37)	8 (13.55)	

[Table/Fig-5]: Factors influencing lack of reporting.
(p-value <0.05 is statistically significant calculated by chi-square test.)



[Table/Fig-6]: Overall awareness, attitude and practice of Materiovigilance among responders based on median scores of each domain.

of Materiovigilance i.e., Central Drug Safety Control Organisation (CDSCO) which is also national authority of pharmacovigilance. Knowledge on risk categories was not up to the mark in the present study which was similar to the results of other studies [3,12]. About 80.45% of participants in the present study had knowledge of medical incident reporting, which is similar to the study done by Omona K at Midigo Health Centre IV (84.1%) [17].

A 56.8% participants knew about reporting methods in study done by Mohamed M et al., whereas 82.18% knew in the present study [18]. The present study and Meher BR et al., suggests that seniority is not a determining factor of awareness of materiovigilance [12]. Reason for lack of awareness may be materiovigilance being a newer concept and since not so much emphasised in the curriculum, it does not come easily in the conscience of doctors [12].

As it is said that knowledge is of no use until it is kept in practice. So, when we talk about key practice items among responders, nearly half of them and in study of Sivagourounadin K et al., nearly 31% have read any article on Materiovigilance which was still unsatisfactory [11]. In study done by Panchal YN et al., and Meher BR et al., 55.6% and 51.9% of faculty have experienced adverse events respectively which was similar to consultants in the present study (50%). But when it comes to reporting, only 9% of Panchal YN et al., and 19% of participants in study of Meher BR et al., have reported the events which was lesser as compared to the present study (45.40%) [3,12]. It may be because medical personnels recognised various challenges in the practice of materiovigilance due to lack of proper adverse event reporting system, lack of conducive environment, and busy schedule.

A study done by Coyle YM et al., found that early exposure of postgraduate medical trainees to the medical education program for medical event reporting had positively affected their reporting attitude [19]. In the study of Aida K et al., almost 9/10th of the surveyed sample (88.5%) whereas in the present study 63.4% of them have never been trained on medical device vigilance [20]. In fact, positive changes in knowledge, skills and attitude would be paramount after education and training courses of professionals (Jansma JD et al., 2011) [21]. There is a need of encouraging "safe device handling after implant" sessions because a lesser number of practising doctors have ever been a part of it till now, which is restraining them to prevent any mislead, if it tend to occur.

Despite lack of awareness and practice, very optimistic attitude was found among doctors related to reporting in future. Belief of "devices can lead to adverse event" and "need of an obligatory reporting it" was emphasised by majority of doctors in the present study. Similar results of positive outlook were observed in participants of Panchal YN et al, Sivagourounadin K et al., Meher BR et al,and Kurien S et al., [3,11,12,22]. It may be because they felt their sense of responsibility and necessity to teach about reporting and create awareness among hospital practitioners for goodness of patients. Whereas Gagliardi AR et al., mentioned that medical personnels had a contrary attitude and believed that reporting adverse occurrences related to medical equipments was superfluous and meaningless. Additionally, they did not see it, as their duty to report negative incidents [23].

Participants of study done by Omona K felt that responders should be educated and should have strong positive feeling to improve patient safety [17]. Lack of time and non existence of convenient reporting system was also felt by 20.8% of consultants and 26.7% of resident doctors according to Kurien S et al., [22]. Likewise, the possible obstacles coming through by majority of participants in this study were noted as time constraints, non availability of hard copies of forms in hospitals, paucity of learning to report and lack of liability felt by doctors. [Table/Fig-7] shows comparative evaluation and inferences of similar studies done at various sites [3,11,12].

Study	State/year of the study	Sample size	Number of questions	Inference
Panchal YN et al., [3]	Gujarat/2021	156	17	Limited knowledge regarding the various aspects of materiovigilance, poor practice, positive attitude
Meher BR et al., [12]	Bhubaneswar, Odisha/2022	138 (45 faculty, 60 residents)	15	Limited knowledge about the Materiovigilance, extremely poor practice, positive attitude
Sivagourounadin K et al., [11]	Puducherry/ 2019	420	15	Adequate level of knowledge regarding the various aspects of materiovigilance, high response rate and positive attitude, factors such as uncertainty on how to report a MDAE and concerns about their legal issues significantly led to underreporting of MDAEs.
Present study	Gujarat/2022-23	174 (54 consultants, 61 Residents and 59 Interns)	26	Adequate awareness, poor practice of reporting, optimistic attitude

[Table/Fig-7]: Comparative evaluation with similar studies [3,11,12].

Hence, the authors believe that creating awareness among all medical personnels altogether irrespective of age or designation is need of an hour, for the goodness of patients and healthcare sector of the state.

Limitation(s)

Present study was performed only on small number of doctors and only of single state, hence, results may not be generalised to all doctors of India.

CONCLUSION(S)

Irrespective of inadequate awareness and practice, optimism in attitude was found in participants of present study. However, the transition of knowledge and attitude to reporting MDAE was lacking. Positiveness in attitude suggests that with due efforts, it is not difficult to improve the healthcare system of society, by strengthening the surveillance of medical devices with the fruitful role doctors in it. There is a need to conduct regular seminars/ workshops/CMEs/training sessions, along with incorporating materiovigilance in the undergraduate or postgraduate curriculum

and make reporting feasible and easy at workplaces, to facilitate the practice of spontaneous reporting by doctors and strengthen the health and welfare system of the country.

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- Manual Googling: Feb 25, 2023
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