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Original Research Article

A study assessing the knowledge, attitude, and practice of materiovigilance among medical professionals in the states of Tamil Nadu and Andhra Pradesh, India

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ABSTRACT

Background: Medical devices are vital for healthcare diagnosis and treatment but pose inherent risks. Physicians and healthcare professionals play a crucial role in reporting adverse events associated with these devices. Despite this, there is a notable scarcity of literature addressing the knowledge, attitudes, and practices surrounding India's Materiovigilance (Mv) Program. This study aimed to evaluate the knowledge, attitudes, and practices of doctors and postgraduate residents in Andhra Pradesh and Tamil Nadu regarding the Materiovigilance program of India (MvPI).
Methods: It was conducted as an observational, cross-sectional study, a structured self-administered Google Form survey was distributed among medical professionals and citizens of Andhra Pradesh and Tamil Nadu. The survey, comprising 22 questions on knowledge, attitudes, and Mv practices, was disseminated via various social networking sites.
Results: Out of 700 doctors and postgraduate residents surveyed, 496 responded, yielding a response rate of 70.8%. The majority (96.8%) acknowledged the potential for adverse events from medical devices, with 91.1% agreeing on healthcare professionals' responsibility to report such events. Despite experiencing medical device-related adverse events in practice (63.3% of respondents), only a small fraction (12.1%) reported them, although 93.5% expressed willingness to report.
Conclusions: The study underscores a knowledge gap among physicians and residents regarding MvPI in India, highlighting the necessity for educational interventions. To address this gap, MvPI coordinators should organize conferences and seminars aimed at enhancing awareness and reporting practices among healthcare professionals.

Keywords: Materiovigilance, Medical devices, Adverse events, MvPI

INTRODUCTION

Any device, equipment, application, instrument, gadget, implant, substance for in vitro use, apps, material, or other similar or related object, designed by the manufacturer to be used, either alone or in combination, for a therapeutic and diagnostic purpose, can be considered a medical device.[1] Medical devices occur in a wide variety of forms, ranging from straightforward gauze, bandage, or syringe needles to complex diagnostic tools like computed tomography (CT) and magnetic resonance imaging (MRI) scanners, pacemakers, and infusion pumps.[2] The notified medical devices list, which provides a list of medical device names that needed to be registered with the Central Drugs Standard Control Organisation (CDSCO) before those devices were marketed. So CDSCO can analyse the devices before consumption by medical professionals, and it will be published by the CDSCO, in New Delhi. Medical gadgets are not fully safe, despite the fact that they are crucial to patient diagnosis, monitoring, and therapy.

Incorrect diagnostic outcomes, injury to the patient's physical and mental health, and occasionally deadly adverse events are only a few of the horrible outcomes caused by several medical devices.[3,4] These incidents produced notifiable morbidity and mortality as a result of unfavorable medical device events. Due to malfunctions, some medical equipment is taken back off the market. Therefore, it is essential to assess medical devices both before and after their commercialization, while also putting strong health monitoring mechanisms in place.[2] The Oxford Dictionary defines "vigilance" as the act or state of keeping a careful watch out for possible dangers or issues. Materiovigilance (Mv) entails close monitoring of any unfavorable changes in a medical device's performance or characteristics using a system that can detect, gather, and report on estimates of unfavorable occurrences and respond to them with device recalls or field safety corrective actions during the post-marketing phase of a medical device.[1] On July 6, 2015, the Indian Pharmacopoeia Commission (IPC), Ghaziabad, hosted the introduction of the Mv programme of India (MvPI) by the DCGI.[5,6] Strive to "increase patient safety and welfare of the Indian population by monitoring adverse events related to medical devices and consequently lowering the risk associated with their usage," as stated in the MvPI's mission statement.[7,8] Additionally, MvPI assisted in gathering data on medical device safety that was ultimately made publicly available for research. Despite the MvPI's eight-year existence, there are surprisingly few articles regarding Mv online. We have undertaken research on the MvPI in terms of knowledge, attitude, and practice.

METHODS

Study population and design

Medical doctors and medical postgraduate residents of Andhra Pradesh and Tamil Nadu state in India. From August 2023 to October 2023, doctors and postgraduate residents in the Indian states of Andhra Pradesh and Tamil Nadu who are actively working with medical devices participated in this observational, cross-sectional, and questionnaire-based study survey. The study was put into motion only after receiving approval from the institutional ethics committee. This study was carried out to assess clinician's awareness and understanding of adverse events caused by medical devices. An English-language structured self-administered Google form-based questionnaire was developed to collect relevant data on the study variables, and it was delivered to the participants through several social networking sites. 22 items on the survey are about Mv knowledge, attitude, and practice. Thirty clinicians working in the tertiary care hospital in Andhra Pradesh were randomly chosen to participate in a pilot study using the project's original version of the questionnaire. A modified survey questionnaire was created for the study based on their ideas and comments. The Institutional Ethics Committee approved the updated questionnaire in its final form. The study questionnaire is divided into two sections in total. Questions about the participants' demographic information (Table 1) make up the first part of the questionnaire. 22 questions about the knowledge, attitude, and practice (KAP) area of Mv made up the second section. The first ten questions were multiple choice questions (MCQs) pertaining to the Mv's knowledge component. We used a scoring system to evaluate the study participants' knowledge, awarding a score of "1" for each accurate response and a score of "0" for each erroneous response. The final 12 questions are divided into two groups: Mv practice in daily life and participant attitudes toward Mv, with six questions focusing on each group. Of the 12 questions, 10 were close-ended and required a "yes" or "no" response, while the other two included a 4-point Likert scale with the options "Strongly agree," "Agree," "Disagree," and "Strongly disagree".[9]

Statistical analysis

The MS Excel spreadsheet was used to enter statistical data, and MS Excel software was used to analyse the data. Continuous data were presented as mean±standard deviation, whilst categorical data were shown as numbers and percentages. To determine whether the two groups differed, we performed a chi-square test on categorical data and an unpaired t-test on continuous data.

RESULTS

A total of 700 participants received the questionnaire, and 496 of them 68 (13.7%) faculty and consultants, 184 (49.1%) MBBS doctors, and 244 (37.2%) postgraduate residents (Figure 1) returned it with all of their answers, representing a 70.8% response rate. Out of 496 responses, 43.3% (215) of respondents were in the 26-30 age range (Figure 2), 66.9% (332) of respondents were from Tamil Nadu, and 33.1% (164), Andhra Pradesh (Figure 3).

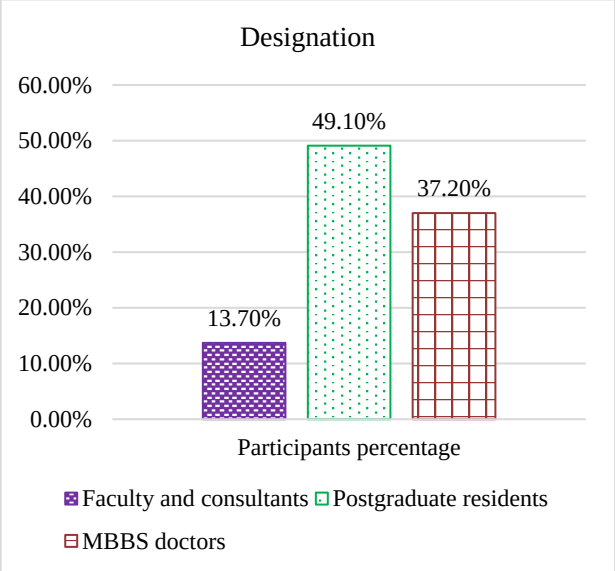

Figure 1: Designation of participants.

Assessment of knowledge

The questionnaire consisted of a total of 10 questions (Table 2) to gauge study participants' Mv knowledge. Out of 496 participants, 57.3% (284) only know that medical devices are categorised according to the risks they pose during clinical usage, and 41.1% (204), only know about the categories of medical devices. Out of 496 respondents, 83.1% (412) are aware of the MvPI, and 92.3% (458) are aware of who can report and how to report adverse occurrences brought on by medical devices. Only 34.7% (172) of respondents are aware of the distinction between unfavourable events that must be reported and those that are not. Only 29% (144) of the respondents are aware of the reporting deadlines for significant adverse events and when to report adverse events. The Mean±SD value of knowledge-based question scores is 5.13±1.67 and 5.58±1.92 for the participants from Tamil Nadu and Andhra Pradesh respectively (Figure 4). There is no significant difference between knowledge-based question scores based on the p value (0.5862) for the participants from Tamil Nadu and Andhra Pradesh ($p<0.05$ was considered statistically significant).

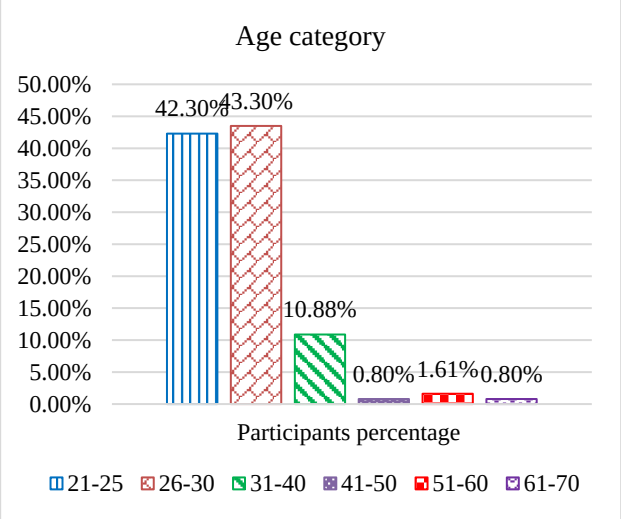

Figure 2: Age category of the participants.

Assessment of attitude

The questionnaire included a total of 6 questions (Table 3) to gauge study participants' attitudes regarding Mv. 480 out of 496 individuals, or 96.7%, agreed that medical gadgets are to account for significant adverse outcomes. 91.1% (452) of participants concur that the community's medical professionals must report adverse events caused by medical devices. Anyone can report adverse incidents caused by medical devices. The majority of participants, 98.8% (490), concur that identifying and resolving medical device-related adverse events will enhance patient safety and medical device quality. 92.3% (458) of participants believe that information on the Mv programme should be given to medical professionals through educational conferences and workshops. Ninety-three per cent (93.5%, or 464) of people are willing to report adverse occurrences caused by medical devices.

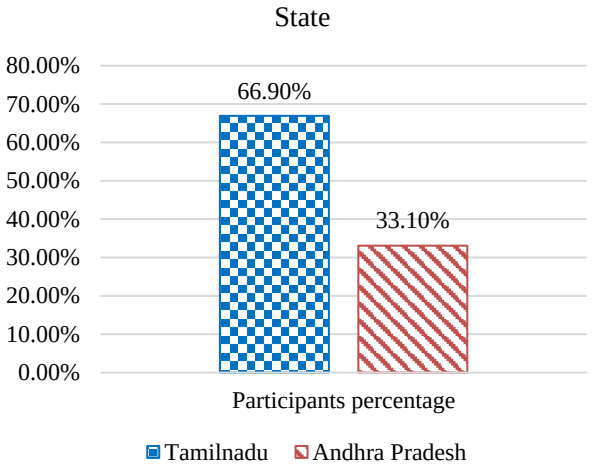

Figure 3: Participants classified based on the states.

Assessment of practice

The questionnaire included a total of 6 questions (Table 4) to gauge how participants in the study practised Mv. 314 out of the 496 individuals, or 63.3%, reported using a medical device and having an adverse incident. However, due to a lack of awareness and understanding of the Mv programme, only 12.1% (60) of participants reported adverse events caused by medical devices during their practice. Only 22.2% (110) of participants knew how to fill out a medical device-induced adverse event reporting form, and only 23% (114) of participants have ever seen one.

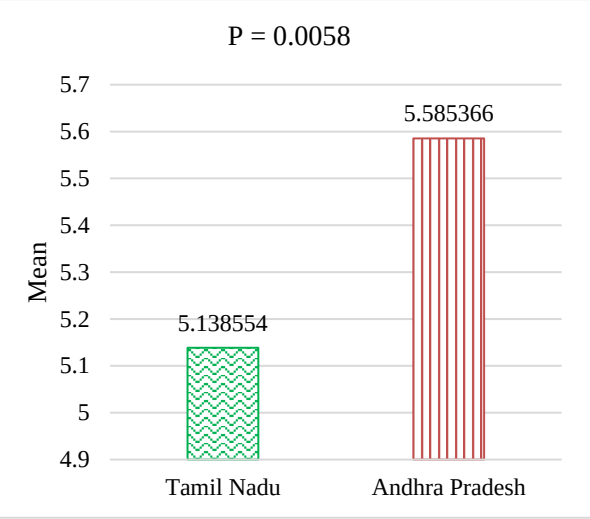

Figure 4: Comparison of mean±standard deviation score of the study participants for knowledge-based question ($p<0.05$ was considered statistically significant).

Table 1: Demographic characteristics of the participants (n=496).

Demographic characteristics	Categories	% (N)
Age (years)	21-25	42.3 (210)
	26-30	43.5 (216)
	31-40	10.88 (54)
	41-50	0.80 (4)
	51-60	1.61 (8)
	61-70	0.80 (4)
State	Tamil Nadu	66.9 (332)
	Andhra Pradesh	33.1 (164)
Designation	MBBS medical officers	37 (184)
	Postgraduate residents	49.1 (244)
	Faculty and consultants	13.7 (68)
Area of speciality	MBBS	36.3 (180)
	MD Anaesthesia	4 (20)
	MD Ayurveda/siddha	1.2 (6)
	MD Community medicine	1.2 (6)
	MD Dermatology	2 (10)
	MS ENT (Oto-Rhino-Laryngology)	2.4 (12)
	MD Forensic medicine	0.4 (2)
	MD General medicine	7.3 (36)
	MS General surgery	3.6 (18)
	DM Medical gastroenterology	0.4 (2)
	MD Microbiology	0.4 (2)
	MS Obstetrics and Gynaecology	1.6 (8)
	MS Ophthalmology	1.6 (8)
	MS Orthopaedics	2 (10)
	MD Paediatrics	4.4 (22)
	MD Pathology	1.6 (8)
	MD Pharmacology	23.8 (118)
	M.ch Plastic surgery	0.4 (2)
	MD Psychiatry	0.4 (2)
	MD Pulmonology / Respiratory medicine	0.8 (4)
	MD Radiology	2.4 (12)
	MD Radiotherapy medicine	0.8 (4)
	M.ch Surgical gastroenterology	0.8 (2)

Table 2: Knowledge of the study participants regarding Mv (n=496).

Questions to assess knowledge	Correct responses, % (N)	Incorrect responses, % (N)
On which basis medical devices are classified into various categories (A, B, C, and D) in India? Based on the risk they carry while their use*, Based on their price, Based on the condition (s)/disease (s) for which they are being used, Based on their complexity of structure	57.3 (284)	42.7(212)
Which of the following medical device belongs to category D? Ventilator, Bandage, Pacemaker*, Orthopaedic implant	41.1 (204)	58.9(292)
What is India's current program for monitoring adverse events caused by medical devices? Medical devices safety program of India, Medical devices single audit program of India, Mv program of India*, Pharmacovigilance program of India	83.1 (412)	16.9(84)
Who can report a medical device-induced adverse event? Doctors only, Nurses, Medical device manufacturer, All of the above*	92.3 (458)	7.7 (38)

Continued.

Questions to assess knowledge	Correct responses, % (N)	Incorrect responses, % (N)
Which is the National Coordination Centre for India's current program for monitoring adverse events caused by medical devices? Indian pharmacopoeia commission*, Central drugs standard control organization, All India institute of medical science, New Delhi, Madras medical college, Chennai	41.9 (208)	58.1(288)
Which of the following adverse event need not to be reported? Surgical gloves causing irritation of the skin, Death of patient due to fire in the incubator, Infusion pump fails to give an appropriate alarm, None of above*	45.6 (226)	54.4(270)
What is a reporting system available in India to report MDAEs (Medical device-induced adverse events)? By toll-free helpline number-1800 180 3024, By Medical Device Adverse Event (MDAE) reporting form, By MDAE Reporting Mobile Application, All of the above*	80.2 (398)	19.8(98)
Which of the following adverse event need to be reported? A patient is admitted to hospital with hypoglycaemia based on an incorrect insulin dosage following a blood glucose result. The investigation found that the test strip was used beyond the expiry date, A patient who is known to suffer from claustrophobia, experiences severe anxiety in the confined space of a MRI machine which subsequently led to the patient being injured, C-arm machine fell down over patient's face in operation theatre due to it's over mobility, even though all fitting techniques were followed from the manual which is given by manufacturers*, All the above	34.7 (172)	65.3(324)
All are partnering organizations of MvPI except? Central Drugs Standard Control Organisation (CDSCO), New Delhi, United Nations International Children's Emergency Fund (UNICEF)*, Indian Pharmacopoeia Commission (IPC), Sri Chitra Tirunal Institute of Medical Science & Technology (SCTIMST), Both United Nations International Children's Emergency Fund and Indian Pharmacopoeia Commission	23.4 (116)	76.6(380)
What is the time period to report serious medical device adverse event? within 10 calendar days, within 15 calendar days*, within 20 calendar days, within 30 calendar days	29 (144)	71 (352)

*Correct response

Table 3: Attitude of the study participants towards Mv (n=496).

Attitude related questions	Response	% (N)
Do you agree medical devices can cause an adverse event?	Strongly agree	57.3 (284)
	Agree	39.5 (196)
	Disagree	2.4 (12)
	Strongly disagree	0.8 (4)
Do you think it is a medical professional's responsibility to report every medical device-induced adverse event?	Yes	91.1 (452)
	No	8.9 (44)
Do you think medical device-induced adverse event reporting should be compulsory?	Yes	95.6 (474)
	No	4.4 (22)
Do you agree that reporting medical device-induced adverse events can improve patient safety and so must be encouraged?	Strongly agree	72.6 (360)
	Agree	26.2 (130)
	Disagree	0.4 (2)
	Strongly disagree	0.8 (4)
Are you willing to report a medical device-induced adverse event?	Yes	93.5 (464)
	No	6.5 (32)
Should Mv be taught in detail to medical professionals?	Yes	92.3 (458)

Table 4: Response of the study participants about the practice of Mv.

Practice related questions	Response	% (N)
Have you ever experienced an adverse event because of a medical device used on any patient during your practice?	Yes	36.7 (182)
	No	63.6 (314)

Continued.

Practice related questions	Response	% (N)
Have you ever reported medical device-induced adverse events during your practice?	Yes	12.1 (60)
	No	87.9 (436)
Do you know about the MvPI?	Yes	35.5 (176)
	No	64.5 (320)
Have you ever been trained on how to report a medical device-induced adverse event?	Yes	16.1 (80)
	No	83.9 (216)
Have you seen the medical device adverse event reporting form?	Yes	22.2 (110)
	No	77.8 (386)
Do you know how to fill medical device adverse event reporting form?	Yes	23 (114)

DISCUSSION

For many years, medical devices were used in the healthcare sector for both diagnosis and therapy. The MvPI was established eight years ago, but due to doctors' lack of Mv expertise, the idea of reporting medical device-induced adverse events still seems novel to the majority of healthcare professionals. Many of them are unaware that our Indian government started the current MvPI to keep track of adverse events brought on by medical devices. Similar to the last point, many of them are unsure about how, where, and to whom to report. Prior research conducted at AIIMS Bhubaneshwar made the same observations.[2]

Due to a lack of knowledge on ADR reporting, adverse events are underreported globally.[4] In the diagnosis, surveillance, and treatment of diseases, medical devices are extremely important. Medical equipment, like drugs, can potentially have negative side effects when used[6]. Regular adverse event monitoring and reporting are essential to limit the occurrence of medical device-induced adverse events and collect data regarding the safety of the medical devices. Medical professionals have access to a large number of articles regarding knowledge, attitude, and practise (KAP) research about pharmacovigilance, however, there are relatively few studies available about Mv.[10,11] As a result, we conducted a KAP study on Mv among doctors as they regularly use medical equipment. Participants in our study lack an understanding of the MvPI and adverse occurrences brought on by medical devices. Only 57.3% of participants are aware of the classification system for medical devices. 58.9% of participants didn't know about the category of medical devices, compared to 69.9% of participants in a study done by Panchal et al [1]. 41.9% of participants could identify the Indian Pharmacopoeia Commission (IPC) as the National Coordination Centre (NCC) of the current Mv programme, compared to 19.2% of participants in a study done by Panchal et al [1]. It demonstrates that participants in both the previous research and the current study lacked information about Mv, although the percentage of persons who knew about the programme was higher than in the earlier investigations, albeit not to the same extent.

According to the participants in our study, everyone is interested in learning about the Mv programme and reporting adverse events brought on by medical devices. 91.1% of participants agree that it is the obligation of medical personnel to report adverse events caused by medical devices, and 96.7% of participants think that medical devices have possible dangers for patients throughout their use. In their future medical practices, 93.5% of participants said they would be willing to report adverse events caused by medical devices. In a study conducted by Meher et al and Kurien et al similar favourable attitude findings were noted. 92.3% of participants recommended that medical professionals should be taught Mv in detail during their undergraduate and postgraduate periods.[2,12] For participants in our study, Mv adverse events reporting is poor. Only 12.1% of participants reported the adverse events, likely because they were unaware of the Mv programme and a lack of knowledge in how to report adverse events caused by medical devices, even though nearly half of the participants had encountered such events in their practice. Only 22% of participants had seen the Mv adverse events reporting form, and only 16.1% of participants had received training on how to complete the form. Many of the individuals didn't take part in any Mv training sessions or report any adverse events brought on by medical devices.

The United States Food and Drug Administration (USFDA) states that only 0.5% of adverse events caused by medical devices are recorded.[13] Compared to medical devices, adverse events that occur by drugs are more likely to be reported by doctors. Physicians are not focusing on locating and analysing adverse events caused by medical devices because of poor reporting mechanisms, the lack of a global or national database to collect and analyse adverse events due to medical devices, and poor ADR reporting environments, particularly in government hospitals due to the heavy patient load and busy schedule.[14] Our study has some constraints at the moment. Our study's sample size was too small and insufficient to allow us to extrapolate the results to a sizable population. Despite these limitations, we are confident that the results of our study will help other healthcare providers report adverse events related to medical devices more accurately and with higher quality.

CONCLUSION

Participants in our study lacked knowledge and experience in Mv and ADR reporting. However, they have demonstrated a favourable attitude toward being familiar with India's Mv programme and reporting adverse events brought on by the medical device, which is comforting[12]. Additionally, in order to raise awareness among all medical practitioners, the administrators of India's Mv programme must hold several conferences, educational sessions, and workshops. Medical students' undergraduate and graduate curricula should cover Mv.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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