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KNOWLEDGE, ATTITUDES AND PRACTICES OF MATERIOVIGILANCE AMONG PHYSICIANS IN A RURAL TERTIARY CARE TEACHING HOSPITAL IN PUDUCHERRY – A CROSS SECTIONAL STUDY

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ABSTRACT

Background: In India, medical devices are considered to be drugs. A medical device may lead to problems either due to a defect during manufacture or transport, improper handling by health care professionals or patients, or failure to comply with recommendations. **Aim & Objective:** To evaluate the knowledge, attitude, and practice of Materiovigilance among health professionals at the Tertiary Care Hospital. **Methods:** This was a cross-sectional questionnaire-based study conducted among 100 medical professionals. The Questionnaire tool is comprised of two parts. The first part contains demographic data, and the second part consists of 15 questions, 5 each pertaining to the knowledge, attitude, and practice domains. Data were analyzed using Graphpad Instat software version 5.0, and results were expressed in descriptive statistics. **Results:** Medical professionals with above average knowledge scores (57 %) and the practice percentage of Materiovigilance (60%) with a positive attitude (72%) towards Materiovigilance. A statistically significant high score was observed between the knowledge scores of professors and residents (p-value - 0.0491). There was no significant difference in knowledge scores between medical, surgical, and pre/para specialties. However, there was a positive correlation between the knowledge and attitude scores of the medical professionals. **Conclusion:** The Knowledge aspect and the practice of Materiovigilance among Physicians in our tertiary care hospital is lacking. However, their positive attitude to reporting adverse events is reassuring.

INTRODUCTION

Medical device usage among Mankind has been dated back as early as 7000 BC [1]. In recent times, medical devices have played an indispensable part in diagnosing, treating, and preventing various diseases [2, 3]. Recent advances in scientific innovations have substantially increased the role of medical devices in the healthcare delivery system. Over a million medical devices are available, from simple, cheap needles to expensive and complex devices like ECMO medical imagery devices and software applications [4,5]. World Health

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Organization (WHO) has defined a medical device as any "An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose" [6].

Despite their versatility, medical devices are not fail-proof. There are several cases where a device has been recalled either because of the defect or because of the significant morbidity and mortality it has caused in users [7-9]. Therefore, it is necessary to evaluate and determine the risks and benefits associated with the device. This can be achieved through a robust monitoring mechanism that is strictly observed in only a few countries. Materiovigilance refers to "careful monitoring of any adverse events resulting from the use of medical devices by the establishment and system that includes the identification, collection, reporting, and estimation of adverse events and their responses or safety corrective actions after their post-marketing phase."

DCG (I) launched the Materiovigilance in India (MvPI) program on July 6, 2015, in the Indian Pharmacopoeia Commission (IPC), Ghaziabad [10]. Unlike Western countries, where reporting of Material Safety is mandatory, in India, it is only voluntary reporting and was initially restricted to 10 devices, which were thought to be of critical importance, with the scope for further inclusion to the list.

Precision devices have led to replacing human techniques in almost all aspects of Health Care Delivery. Medical devices are now also used in homes to monitor health hospitals and seek medical attention if necessary. Currently, more than 2 million different types of medical devices are available in the market globally, depending on the distinct roles and technologies used in developing them [11]. In recent years, concerns over a large number of medical device-associated incidents documented in different countries have emerged, but too few devices have been withdrawn from the market, raising the question of the safety of medical devices and their regulation. In India, fatalities and serious adverse effects have been reported, which have raised issues on the quality of health care and its delivery in the country. During the Covid Pandemic, several reports of counterfeit and substandard products invaded the market, and the Government of India has also added Personal Protection Equipment to the list of medical devices and a PPE form to report safety issues arising out of their use [7-9] making the need for monitoring these devices imperative.

The success of National Health Programs rests on the participation of Stakeholders. The MVPI program's success depends on clinicians, biomedical engineers/clinical engineers, hospital technology managers, pharmacists, nurses, technicians, and medical device manufacturers. For any program to be effective, sensitization of the end users needs to be given the most importance. With this background, we started this study to evaluate the knowledge, attitude, and practice of Materiovigilance among health professionals at the Tertiary Care Hospital.

METHODOLOGY

The study was a Cross-Sectional Questionnaire Based study. The survey was done among medical professionals (Professors of all grades and resident doctors) who are handling different types of medical devices at a rural tertiary care teaching hospital at Puducherry (Sri Venkateshwaraa Medical College Hospital & Research Centre).

Inclusion Criteria: All Medical professionals whose services involve using different types of medical devices in our hospital were included in our study, after they consented to participate in the study.

Exclusion Criteria: Medical professionals (Interns) who do not practice using different types of medical devices in our hospital were excluded.

The study was conducted after obtaining approval from the Ethics committee (IEC No. 26/SVMCH/IEC/1120). The questionnaires were circulated among 100 medical professionals, and 75 of them responded. The response rate was 75%. The structured survey tool consisted of two parts. The intro part had questions about the demographic details, and the second part consisted of 15 questions, with 5 each about the awareness, attitude, and practice domains of Materiovigilance among medical professionals. Content validity was carried out using an expert panel, and the study tool was tested on 10 participants to assess the appropriateness, relevance, and comprehensibility of questions. Cronbach's alpha was calculated to be 0.6. The designed structured questionnaire was administered to the professionals who consented to the study after explaining its purpose. Thirty minutes were given to the respondents to fill out the questionnaire. A scoring system assessed the awareness

component. A score of 1 is assigned for each correct answer and zero for the wrong one. Positive attitude and practice were scored 1, whereas negative attitude and practice responses were given a zero. Mean scores were then calculated.

Statistical Analysis

All the data were entered in Microsoft Excel and analyzed using GraphPad Instat software version 5.0. Descriptive statistics are expressed as Mean ± SD, and categorical data (sex, age group, qualification, and designation) are represented as proportions. The data has been checked for normality, and comparisons between and within the groups of knowledge scores were assessed using a t-test for continuous data. The mean awareness score was related to demographics for any association. Similarly, the scoring of attitudes was also correlated for association with qualification and designation of the participants for significant r and p values of < 0.05.

RESULTS

The questionnaires were circulated among 100 medical professionals, and 75 of them responded. The response rate was 75% from all the broad specialty departments. Each representative department collected at least a minimum of 2 responses.

DEMOGRAPHIC CHARACTERISTICS:

Table 1: Demographic characters of the study participants.

S No	Parameter	N =75 n (%)	
1	Gender	Male 35 (47) Female 40 (53)	
2	Designation	Professors 6 (8)	
		Associate Professors 4 (5)	
		Assistant Professor 32 (43)	
		Residents 33 (44)	
3	Departments	Medical 30 (40)	
		Surgical 23 (31)	
		Pre & Para Medical 22 (29)	
4	Age group	< 30	33 (44)
		30-50	41 (55)
		50-70	1 (1)
5	Experience	1-2 years	33 (44)
		2-5 years	32 (43)
		5 -10 years	8 (10)
		10 years and above	2 (3)

Table 2: Assessment of knowledge component of Materiovigilance

Knowledge-based question	Correct response N (%)
What is the ongoing program in India for monitoring and reporting adverse events due to medical devices?	45 (60)
What is the basis of categorizing medical devices into A, B, C, and D in India?	42 (56)
Which is a category B medical device?	30 (40)
Which of the following adverse events due to the device need not be reported?	26 (34)
Where can adverse events due to medical devices be reported?	29 (38.6)

With respect to the correct responses to the knowledge questions, basic knowledge about the materiovigilance program was there in 60% of faculties, but the knowledge regarding the category of medical devices and how and where to report such events is inferior, with only 30-40% of physicians knowledgeable. Hence, the average correct response percentage for knowledge questions is 45 %, which needs improvement.

Table 3. Mean Knowledge scores for each component of the study questionnaire knowledge mean -total score obtained

S No	Overall score	N=75 (%)
1	0	17 (22.6%)
2	1	15 (20%)
3	2	18 (24%)
4	3	16 (21.4%)
5	4	9 (12%)
6	5	0 (0%)

With respect to the attitude of the physicians towards adverse events caused by medical devices, it shows a positive trend, with an average of more than 95% having a positive attitude to responding to and reporting adverse events. With reference to the practice-related questions, the number of physicians who have come across such adverse events due to medical devices was less (20%), and hence, the reporting percentage is also less (13%). The number of physicians who have attended CMEs or awareness programs on vigilance and ADR reporting is also less (6%).

Table 4: Frequency distribution of attitude response towards Materiovigilance

Question	Response n (%)	
	Yes	No
Do you think adverse events can occur in patients due to medical devices?	70 (93.3)	5 (6.67)
If yes, do you think reporting the same is necessary?	73 (97.3)	2 (2.7)
Do you think doctors must report such adverse events?	71 (94.7)	4 (5.3)
Should all the doctors be trained to report adverse due to medical devices?	73 (97.3)	2 (2.7)
Will reporting of such adverse events increase patient safety?	75 (100)	0 (0)

Table 5: Frequency distribution of Practice response of Materiovigilance

Question	Response n (%)	
	Yes	No
Have you come across any adverse events due to medical devices in your practice?	15 (20)	60 (80)
Have you reported any type of adverse events due to devices to date in your practice?	10 (13.33)	65 (86.67)
Will you monitor patients for any adverse outcome of implanted medical devices beyond recovery?	35 (46.7)	40 (53.33)
Will you collect any feedback for adverse events from patients after implanting the medical devices?	39 (52)	36 (48)
Have you ever attended a medical device safety workshop or CME?	5 (6.6)	70 (93.4)

Table 6: Comparison of mean knowledge score among medical professionals

Educational Qualification	Mean knowledge score	p value
Professor	2.06	0.1527
Asst/Assoc Prof	2.47	
Senior Residents	1.8	0.0491
Junior Residents	1.6	

A significant difference was noted Between professors and residents (p-value - 0.0491). Residents had lower knowledge scores compared to professors. The source of knowledge for professors was through Pharmacovigilance activities like CMEs and a celebration of Pharmacovigilance Awareness weeks through the ADR monitoring center of our institute.

Table 7: Comparison between medical and surgical specialties

Specialization/ field	Mean knowledge score	p value
Medical	2.16	0.7580
Surgical	1.9	
Pre/para clinical	2.23	

There was no significant difference in knowledge scores between medical, surgical and pre/para specialties.

Table 8: Correlation analysis

Parameter	R-value (r^2)	95% C. I.	p-value
Knowledge vs Attitude score	0.4851 (0.2354)	0.2390 – 0.6727	0.0004
Knowledge vs practice	-0.04535 (0.002)	0.3197-0.2360	0.7545
Attitude vs practice	0.2493 (0.062)	-0.0313 – 0.4934	0.0809

There was a positive correlation between the Knowledge and attitude scores of professionals (Fig. 1)

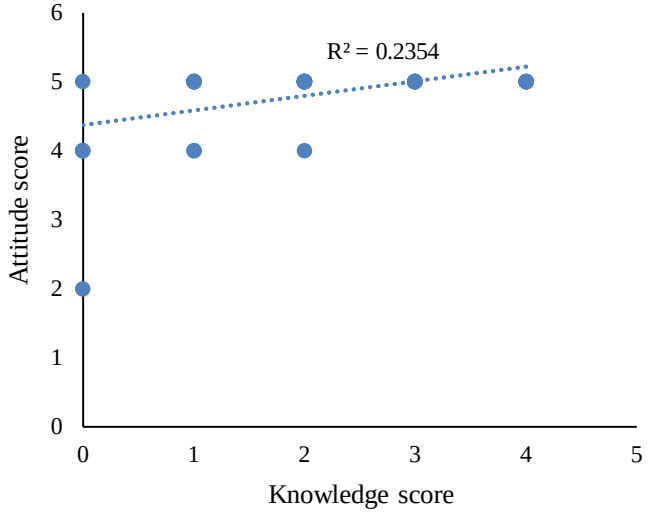

Figure 1: Correlation analysis Scatter plot

DISCUSSION

In India, medical devices are considered as drugs. The CDSCO does regulation of medical devices, similar to drugs [11,12]. A medical device may lead to problems either due to a defect during manufacture or transport, improper handling by health care professionals or patients, or failure to comply with

recommendations. Adequate knowledge of these factors is needed to identify adverse effects due to devices. A total of 897 adverse medical device-related events were reported in India in 2019, which is still less than in other countries [13]. Materiovigilance is a new entity, and it is possible that it is still in its infancy in India. Stakeholder involvement, especially medical professionals, needs to know about materiovigilance in order to fulfill the role of MvPI, which is to practice safe and effective use of medical devices by examining their risk-benefit ratio and, in turn, educate the patients. Among the respondents, 2/5th (40%) of the doctors were not aware of the current MvPI initiated by the Indian Government to monitor Medical Devices associated with Adverse Events (MDAE). Two-thirds of them (66%) were unaware of the type of adverse events to be reported, and (61.4%) of respondents did not know where to report them. In a study conducted among staff nurses, 67% knew about the existence of MvPI program, which is higher than that observed in our study [14]. With respect to the correct responses to the knowledge questions, basic knowledge about the materiovigilance program was there in 60% of faculties, but the knowledge regarding the category of medical devices and how and where to report such events is very poor, with only 30-40% of physicians knowledgeable.

Hence, the average correct response percentage for knowledge questions is 45 %, which needs improvement. It may be, because the medical professionals were not yet familiar with materiovigilance, unlike pharmacovigilance. There was a significantly better awareness/ knowledge score for Professors when compared to residents, which may be due to regular updating of information by attending Pharmacovigilance CMEs, awareness weeks conducted routinely by ADR monitoring center as part of National Pharmacovigilance week which is celebrated every year in the month of September. To further improve MDAE reporting, Shukla et al. 2020 proposed that education on MDAE and its reporting be introduced to undergraduate and post-graduates in the healthcare profession [15]. In studies done by Meher BR et al., 68.4% of respondents had knowledge of the MVPI Programme, which is comparable to our study [16]. Underreporting of MDAE has been found in other countries as well [17-19]. It has been found that small training sessions involving small groups of healthcare professionals at regular intervals has led to improved reporting of MDAE [20]. Another reason for more underreporting percentage, could be due to the fact that we could not get enough respondents from superspeciality fields and Emergency Department whom are much more likely to handle medical devices more than their other counterparts introducing a non - response bias. Like in other studies, lack of time is the predominant reply for non-return of response sheets among these doctors in our study [17].

In our study medical professionals with an adequate knowledge about materiovigilance also had a positive attitude towards reporting of MDAE (Positive correlation was there between Knowledge and attitude scores). We can expect improved reporting as more than 90% of doctors agreed that they should be trained about medical device adverse events. Hence positive correlation implies that with frequent educational CMEs, workshops, better framework and guidance will in turn drive the medical professionals for a better practice of reporting all types of adverse events due to medical devices and enhance patient safety. A Limitation of our study was that it was conducted in only one institution with a small population of medical professionals, which may not be a true representation of all medical professionals in the country. One reasoning is that, advanced care centers and super specialty centers are more likely to use more number and a variety of medical devices and hence ours being a tertiary center with super specialty doctors constituting 5% of the study population; this result can be extrapolated to teaching hospitals in the country as compared to specialty centers who would be knowledgeable about devices and its adverse effects and reporting systems.

CONCLUSION

Based on the present study, we observed that medical professionals with adequate knowledge of materiovigilance also had a positive attitude towards reporting MDAEs. Among the participants, 2/5th of doctors did not know about the current MvPI. Thus, we conclude that the knowledge and practice of Materiovigilance among medical professionals in our tertiary care hospital is lacking. However, their positive attitude to reporting adverse events is reassuring. Since they have a positive attitude, they can be guided to attend CMEs, hands-on training and awareness programs on ADR monitoring and reporting, to promote reporting practice of adverse events and to disseminate the knowledge of materiovigilance among other professionals. Further, we suggest expanding the existing ADR monitoring centers to include MDAE reporting to make the Materiovigilance program a grand success.

FINANCIAL ASSISTANCE
Nil

CONFLICT OF INTEREST
The authors declare no conflict of interest

AUTHOR CONTRIBUTION
Sakthibalan M, Mangaiarkkarasi A, and Indumathi C designed the research work, collected data, and made necessary corrections and revisions in the manuscript. All the authors contributed their expertise and framed the final manuscript.

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