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Enhancing patient safety through effective materiovigilance system: a prospective observational study on adverse events reporting for medical devices in surgical and orthopaedic departments at a multispecialty hospital

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ABSTRACT

Background: Medical device-associated adverse events (MDAEs) pose serious risks to patient safety, still its underreporting. The Materiovigilance Programme of India (MvPI) was established to systematically monitor and improve the safety of medical devices. The objective of this study was to enhance patient safety by identifying and analyzing adverse events associated with medical devices and to evaluate healthcare professional's knowledge about materiovigilance.
Methods: A 6-month prospective observational study was conducted at Kovai Medical Centre and Hospital, Coimbatore. MDAEs were recorded and classified under MDR 2017 guidelines. Causality, severity, and risk class were analyzed. A structured questionnaires assessed knowledge, perception, and barriers among 121 healthcare professionals.
Results: Among 40 MDAEs, 52.5% involved class C (high-risk) devices like orthopaedic implants, all classified as serious. Significant correlation was found between device class and severity (p=0.0001). Causality assessments showed most events were probable or related. Survey results showed 78.5% awareness of MvPI, yet only 34.7% had reported MDAEs.
Conclusions: The study emphasizes the need for improved training, simplified reporting procedures, and institutional support to enhance materiovigilance. Strengthening MvPI with user-friendly tools, confidentiality measures, and feedback systems is crucial to ensuring safe medical device usage.

Keywords: MvPI, Medical device adverse events, Orthopaedic implants, Post-marketing surveillance, Surgical devices

INTRODUCTION

Materiovigilance refers to the systematic monitoring, assessment, and response to adverse events related to medical devices during their post-marketing phase.[1] Similar to pharmacovigilance for drugs, materiovigilance ensures patient safety by identifying and mitigating risks associated with medical devices. Medical devices range from basic items like bandages to complex technologies such as MRI machines and surgical implants.[2] Robust monitoring is essential for early detection of potential device-related hazards. India lacked a formal system to record medical device-related adverse events (MDAEs) until reports of faulty implants and substandard devices prompted regulatory action.

In 2015, the Indian Pharmacopoeia Commission (IPC) was authorized to coordinate the Materiovigilance Programme of India (MvPI), with support from the Central Drugs Standard Control Organization (CDSCO), Sree Chitra

Tirunal Institute for Medical Sciences and Technology (SCTIMST), and the National Health Systems Resource Centre (NHSRC).[3] Medical device regulations were later established under the Medical Device Rules (MDR) 2017, which classified devices into four risk categories: Class A (low risk), Class B (mild to moderate risk), Class C(moderate to high risk), Class D (high risk).[4-6] MvPI aims to collect, analyze, and utilize data on MDAEs to support regulatory decision-making and improve device safety. It also seeks to raise awareness among healthcare professionals and promote safe practices through structured reporting systems. The integration of artificial intelligence and robotics in modern medicine further emphasizes the need for vigilant monitoring due to emerging risks from technological errors.

METHODS

Aim and objectives

The aim of the study was to enhance patient safety by implementing effective materiovigilance practices in surgery and orthopaedics. Objectives include identifying common MDAEs, categorizing these events, understanding barriers to reporting, and promoting preventive measures to avoid recurrence.

Methodology

After getting the approval from IHEC conduct a prospective observational study at Kovai Medical Centre and Hospital, Coimbatore. Patients undergoing surgical or orthopaedic procedures involving medical devices will be enrolled based on convenience sampling. Inclusion criteria cover patients of all ages receiving relevant care and healthcare professionals involved in the MvPI awareness programme. Exclusion criteria include adverse events unrelated to devices or insufficient data for assessment.

Study period

The study period was November 2024 to April 2025.

Sample size

The sampling was convenience sampling.

Statistical analysis

Data will be entered in Microsoft Excel 2016 and analysed using IBM SPSS statistics version 29. Descriptive statistics will summarize categorical and continuous variables. Chi square tests will determine significance in qualitative data, with p value<0.05 considered statistically significant.

Study plan

Patients meeting inclusion criteria will be enrolled and assessed using standardized tools for categorizing MDAEs. Root causes will be identified and documented. Ongoing patient monitoring will guide risk management. Workshops will be held to increase awareness of MvPI among healthcare professionals and promote MDAE reporting. The outcomes will help refine materiovigilance practices and enhance overall patient safety.

Ethical consideration

The present study was approved by the IHEC of the KMCH Institute of Allied Health Science and the study no: 25/IHEC/03.

RESULTS

Observational analysis

Gender distribution

The dataset consists of 32 individuals. Of these, 19% (6 individuals) are female, while 81% (26 individuals) are male. Demography was not recorded for near miss events.

Age distribution

The distribution of MDAE across age groups demonstrates a notable age-related trend and all patients were categorized based on the age group. The incidence of MDAE was highest in 61-70 age group has the highest number of MDAE (n=7 cases), followed by the 71-80 group with (n=6 cases) and the least affected groups were 1-10 and 51-60, indicating age-related variation in device-related incidents.

Experimental analysis

Medical devices (MDs) frequently associated with MDAE

In total, 40 distinct medical devices associated with AEs and their frequency were shown in Figure 1 among these, endotracheal tubes were the most frequently documented, accounting for 15% (n=6) of the total cases. Femur implants, knee implants, and silicone Foley catheters each constituted 12.5% (n=5) of the devices recorded. Hip implants represented 7.5% (n=3) of the total. Additionally, a variety of devices were observed in single instances, each comprising 2.5% (n=1) of the dataset. These included DJ stents, IVC filters, laryngoscope, patella implants, phalangeal implants, Premi Cath with stylet, coronary artery bypass graft (CABG) retractors, right femoral nails, right humerus implants, sigmoidoscope, sutures (used either alone or in combination with anchors), tibial plating devices, ulna-radius implants, umbilical catheters, and wrist implants.

Adverse event causality assessment

Out of the 40 adverse event reports analyzed (Figure 2), a majority (n=31, 77.5%) were assessed as either probable (n=16, 40%) or related (n=15, 37.5%), suggesting a strong

or definite causal link to the suspected agent or intervention. Possible associations accounted for 20% of cases (n=8), indicating an uncertain but plausible relationship. Only a single case (2.5%) was determined to be Not related to the intervention. These findings indicate that the majority of reported incidents had a significant likelihood of being causally linked, underscoring the importance of systematic evaluation and prompt reporting of such events.

Medical device adverse events: incidence trends and clinical responses across multiple device classes

Documented medical devices (n=40) were classified into class A, B and C according to Medical Device Rule (MDR) 2017 approved by CDSCO.[5,6] This observational summary categorizes adverse events (AEs) associated with medical devices across Classes A, B, and C (Table 2). Class A (n=1) devices, such as surgical retractors used in CABG, presented with minor complications like sternal wound discharge, managed conservatively. Class B (n=18) included commonly used devices such as catheters, endotracheal tubes, and tracheostomy tubes. Reported AEs involved functional issues, infections, and leakage, predominantly managed by device replacement or conservative treatment. Class C (n=21) encompassed orthopaedic implants with serious complications including implant loosening, infection, periprosthetic fractures, and mechanical failures. These frequently necessitated surgical interventions such as implant removal, revision surgery, or fracture fixation. The findings emphasize the importance of post-market surveillance and tailored clinical responses to device-related complications.

Device risk classification and severity of adverse events

This study analysed the relationship between device risk classification under India's Medical Device Rules (MDR) 2017 and the severity of adverse events (AEs). A total of 40 events were reported, classified as non-serious (n=11, 27.5%) and (n=29, 72.5%) serious (Figure 3).[5,6]

Class A

Of the total events, (n=1, 2.5%) was related to class A devices, and it was classified as a non-serious event.

Class B

Class B devices accounted for (n=18,45%) events, with (n=10, 25%) non-serious and (n=8, 20%) serious events.

Class C

Class C devices contributed (n=21, 52.5%) events, all of which were serious.

The Chi-square test revealed a statistically significant association between device risk classification and event severity (Pearson Chi-square=17.708, p=0.0001). This indicates that higher-risk devices (Class B and C) were more likely to be associated with serious adverse events.

Evaluation of awareness, knowledge, attitude, perception and barriers about MDAE among healthcare participants

A predesigned, Google form questionnaire, in English language, was created by the researchers after reviewing the literature. Then questionnaire was sent to participants (students, nurse, interns, pharmacist, other healthcare professionals) using WhatsApp social media platform. Questionnaire included demographic details of participants with 10 questions. Among the 121 participants included in the study, the majority were female (n=79, 65.3%), while male participants accounted for 34.7% (n=42) (Table 3).

Participants represented a range of healthcare roles, with nurses comprising the majority (n=62, 51.2%). Students accounted for 25.6% (n=31), followed by pharmacists (n=14, 11.6%) and interns (n=10, 8.3%). A smaller proportion of participants were physician assistants (n=3, 2.5%) and dietitians (n=1, 0.8%) (Table 4).

Awareness and experience related to materiovigilance among healthcare participants

Creating the awareness among the healthcare professionals to enhance their understanding of MvPI and to provide guidance on how to report MDAEs using the prescribed format. The program covered essential aspects such as how to identify, document, and where to report MDAEs. In terms of awareness and experience, 78.5% of respondents were aware of the Materiovigilance Programme of India (MvPI), while only 34.7% had previously reported an adverse event related to medical devices. Despite the high level of awareness, just 63.6% reported knowing the actual procedure for reporting such events. Additionally, 48.8% of participants had received some form of training in materiovigilance, while 51.2% had not, indicating a gap in formal education or institutional support regarding adverse event reporting (Table 5).

Attitude and perception among healthcare participants

When asked about the impact of adverse event reporting, a significant proportion of participants (66.9%) strongly agreed, and 31.4% agreed that reporting improves patient safety. Only 1.7% were neutral, and none disagreed with this statement.

However, concern over possible consequences of reporting was evident, with 38.8% expressing fear of blame or legal repercussions. Regarding the burden of the reporting process, 44.6% of participants found it time-consuming, whereas 55.4% did not perceive it as a major burden (Table 6).

Barriers to reporting among healthcare participants

Barriers to reporting were also explored. The most frequently reported barrier was a lack of awareness about how to report adverse events (19%). Other frequently mentioned challenges included fear of legal consequences, unclear reporting processes, lack of feedback after reporting, lack of time due to workload, and lack of support from management.

A small-proportion of respondents believed that certain events were insignificant and therefore not worth reporting. Additionally, 38% of participants indicated that they had faced difficulty accessing the MvPI reporting form, suggesting a need for improved accessibility and user-friendly tools for reporting.

Regarding confidentiality, 71.9% of respondents believed that anonymity should be ensured in the reporting process, which underscores the importance of establishing a non-punitive reporting environment. Suggestions for encouraging better reporting practices included regular training and workshops (17.3%), providing feedback on reported events, simplifying reporting forms, ensuring confidentiality, and offering incentives. Among these, regular training and workshops emerged as the most frequently cited measure. A minority also recommended reducing the time required for reporting as a motivating factor (Table 7).

Table 1: Device risk classification.

Class A (low risk)	Class B (low-to-moderate risk)	Class C (moderate-to-high risk)	Class D (high risk)
Surgical dressing, suture, alcohol swabs, thermometers, nasopharyngeal swabs, tongue depressors, umbilical occlusion device	Atrioventricular shunt, transcervical endoscope, oximeter catheter, hypodermic needles, suction equipment, hematology reagent kits, disinfectants, intravenous catheter, rectal catheter, fistula adapter	Uterine balloon therapy device, vein ablation device, intraocular lenses, lung ventilator, bone fixation plate, biliary stents, bone cement	Coronary stent, cardiac stents, implantable defibrillator, cochlear implants, heart valve, copper T

Table 2: List of MDs along with incidence and corrective actions of MDAE (n=40).

Class	Incidence	Corrective action
Class A devices (low-risk)		
Medical device	MDAE (Incidence)	Corrective action
Retractor (CABG)	Sternal wound discharge	Conservative management
Class B devices (Low-to moderate risk)		
Medical device	MDAE (Incidence)	Corrective action
Sigmoidoscopy	Surgical site bleeding	Conservative management
Rush foley catheter	Balloon could not inflate	Catheter replaced
Subglottic endotracheal tube	Cuff not inflated properly; leakage	Tube replaced
Silicon foley catheter	Leakage due to damaged line	Catheter removed and replaced
Laryngoscope	Suction apparatus malfunction	Replaced
Silicon foley catheter	UTI, haematuria, fever	Conservative management
Catheter (unspecified)	Periurethral urine leakage	Catheter replaced
Premi Cath with Stylet	Leakage after 3 days of insertion	Removed
IV filter	Leakage on connection	Removed
Umbilical catheter	Catheter damage	Removed
Tracheostomy tube	Cuff damage	Tube replaced
Endotracheal tube	Lower respiratory tract infection	Conservative management
Sutures	Surgical site bleeding	Conservative management
Sutures and Anchors	Post-op stiffness and shoulder pain	Rotator cuff repair
Tracheostomy tube	Inner cannula non-fenestrated during surgery	Removed and replaced
Tracheostomy tube	Cuff damage	Removed and replaced
Urinary catheter	Catheter-induced UTI	Conservative management

Continued.

Class	Incidence	Corrective action
Medical device		
Retractor (CABG)	Sternal wound discharge	Conservative management
Class B devices (Low-to moderate risk)		
Medical device	MDAE (incidence)	Corrective action
Sigmoidoscopy	Surgical site bleeding	Conservative management
Class C devices (moderate-to high risk)		
Medical device	MDAE (incidence)	Corrective Action
Hip implant	Right hip pain	Implant replacement
Knee implant	Aseptic loosening (right TKR)	Implant replacement
Knee implant	Infection, pain, swelling (left TKR)	Revision surgery
Hip implant	Surgical site infection	Conservative management
Wrist implant	Dislocation, pain, immobility	Revision surgery
Femur implant	Periprosthetic fracture	Complex fracture fixation
Right mega prosthesis	Pain, surgical site infection	Reconstruction
Right femur implant	Screw broken	Implant removal
Ulna radius implant	Severe pain in forearm	Implant removal
Right femoral nail	Surgical site ooze, fever	Conservative management
Hip implant	Periprosthetic fracture due to injury	Fracture fixation
Knee implant	Infected TKR	Wound debridement
Tibia plating	Severe pain and infection	Implant removal

Table 3: Gender distribution of participants (n=121).

Gender	Frequency (n=121)	Percent (%)
Female	79	65.3
Male	42	34.7

Table 4: Designation of participants (n=121).

Designations	Frequency (n=121)	Percent (%)
Nurse	62	51.2
Student	31	25.6
Pharmacist	14	11.6
Interns	10	8.3
Physician Assistant	3	2.5

Table 5: Awareness and experience related to materiovigilance among healthcare participants (n=121).

Questions	Response	Frequency (N)	Percent (%)
Have you reported an adverse event before?	No	79	65.3
	Yes	42	34.7
Are you aware of the Materiovigilance Programme of India (MvPI)?	No	26	21.5
	Yes	95	78.5

Table 6: Awareness and experience related to materiovigilance among healthcare participants (n=121).

Questions	Response	Frequency (N)	Percent (%)
Do you believe reporting adverse events improves patient safety?	Agree	38	31.4
	Neutral	2	1.7
	Strongly agree	81	66.9
Do you feel that reporting adverse events could lead to blame or legal consequences?	No	74	61.2
	Yes	47	38.8
Do you think reporting adverse events is time-consuming?	No	67	55.4
	Yes	54	44.6

Table 7: Barriers to reporting related to materiovigilance among healthcare participants (n=121).

Questions	Response	Frequency (N)	Percent (%)
Barriers to reporting	Lack of awareness about how to report	23	19.0
Difficulty accessing MvPI form	No	75	62.0
Anonymity in reporting	Yes	87	71.9
Measures to encourage reporting	Regular training and workshops	21	17.3

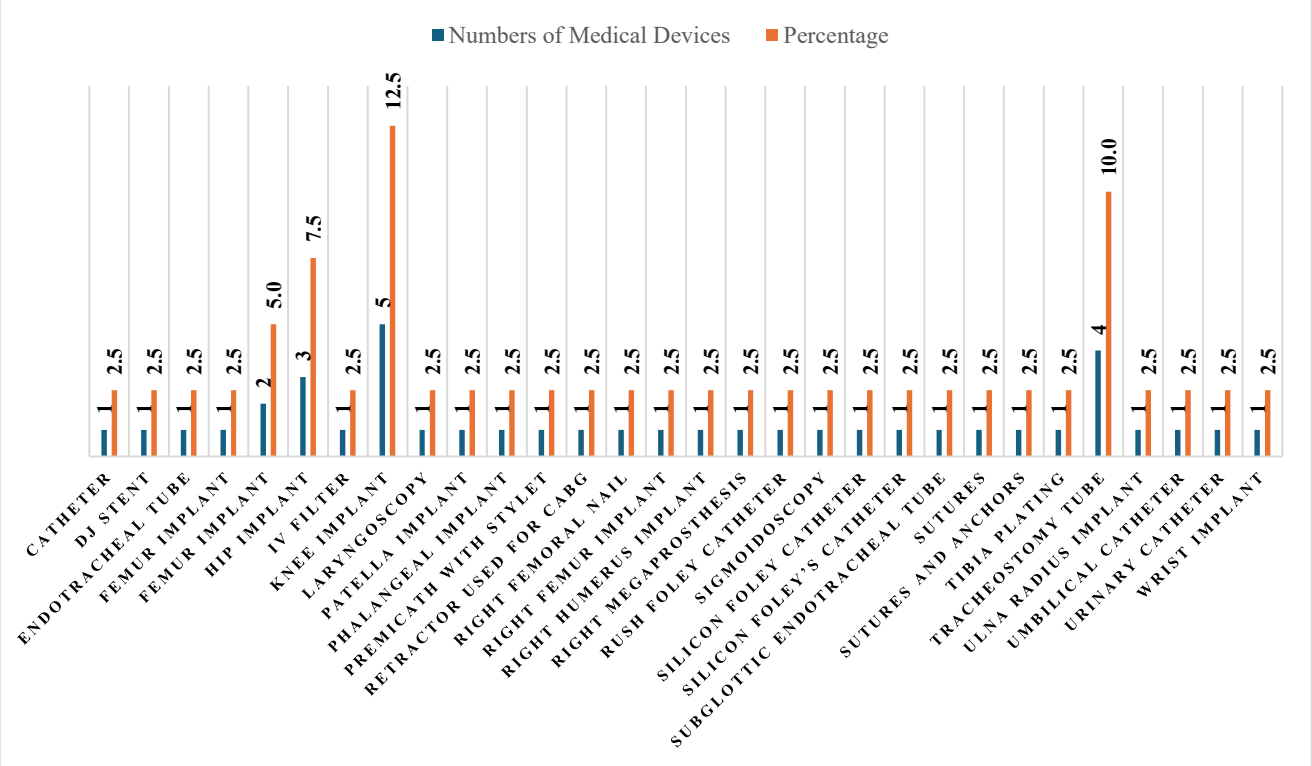


Figure 1: Frequency of medical devices (MDs) associated with adverse events (n=40).

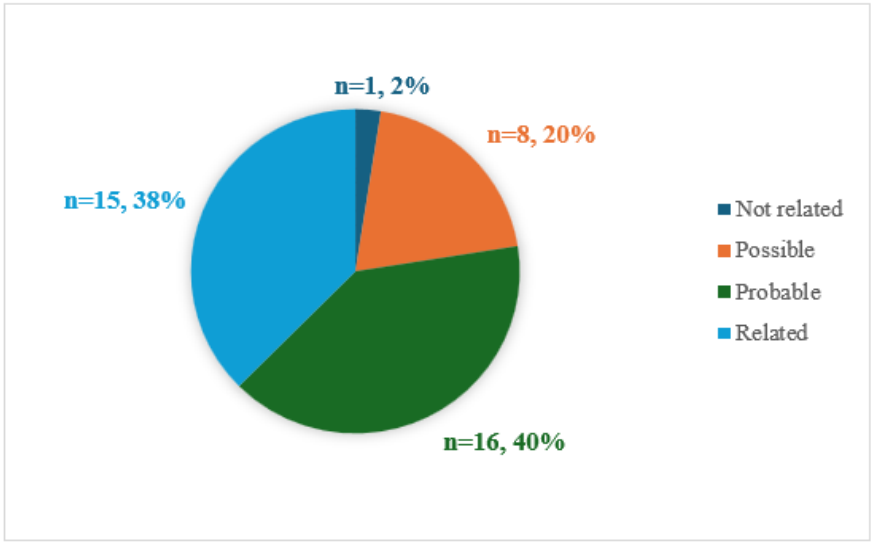
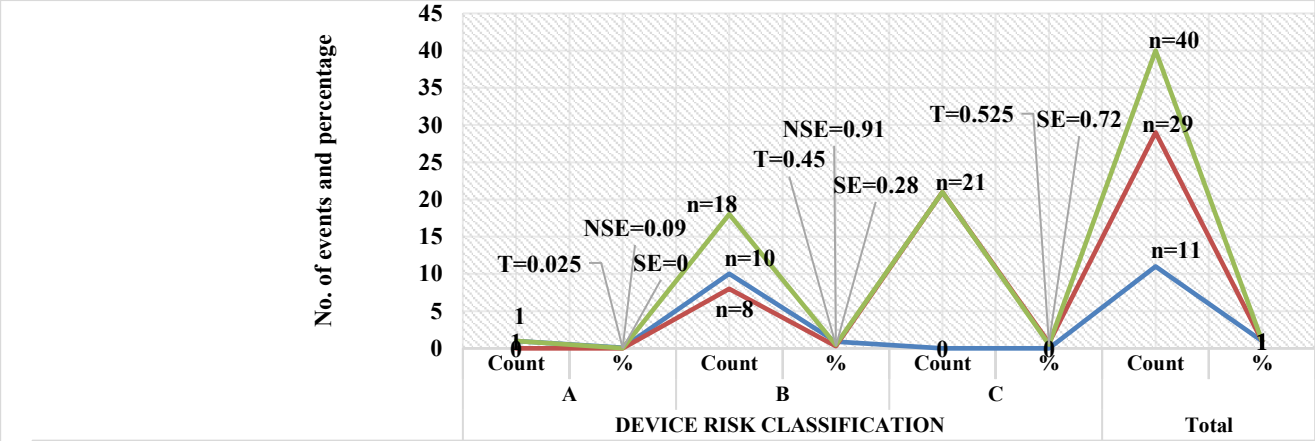


Figure 2: Casualty assessment (n=40).



	A Count	A %	B Count	B %	C Count	C %	Total Count	Total %
EVENT DESCRIPTION Non Serious Event	1	0.09	10	0.91	0	0	11	1
EVENT DESCRIPTION Serious Event	0	0	8	0.28	21	0.72	29	1
Total	1	0.025	18	0.45	21	0.525	40	1

Figure 3: Comparison between risk classification and types of events (n=40).

*P=0.0001 statistically significant calculated by the Pearson Chi-square test. T, total; SE, serious event; NSE, non-serious event.

DISCUSSION

We found 40 MDAE, in that 19% (6 individuals) are female, while 81% (26 individuals) are male and remaining demography data was not recorded for near miss events. The majority of Medical Device Adverse Events (MDAEs) were reported in the 61-70(n=7) and 71-80 (n=6) age groups, together accounting for over 40% of cases. The least affected groups were 1-10 and 51-60, indicating age-related variation in device-related incidents. Similarly Saifuddin et al highlights the gender distribution and missing demography that was not recorded for near miss events and age wise distribution.[7]

This study offers critical insights into the characteristics, severity, and reporting patterns of medical device-associated adverse events (MDAEs), along with healthcare professionals' awareness, attitudes, and practices regarding the Materiovigilance Programme of India (MvPI). A total of 40 MDAEs were documented, with the most frequently implicated devices being endotracheal tubes (15%), followed by femur and knee implants and silicone Foley catheters (each 12.5%). Hip implants accounted for 7.5% of events, while several other devices- such as CABG retractors, DJ stents, and wrist implants- were involved in isolated incidents (2.5% each). These findings are consistent with existing literature that highlights frequent complications with orthopaedic implants and airway management devices.[9,12,15] Adverse events were categorized according to India's MDR 2017. Class A devices accounted for 2.5% of events, class B for 45%, and class C for 52.5%. All class C events were classified as serious, in contrast to class A, which involved only non-serious events. A statistically significant association was found between device risk classification and the severity of the adverse event (Chi-square=17.708, p=0.0001), emphasizing the higher risk profile of Class B and C devices. This is in line with the observations of who reported similar risk-based variations in adverse event outcomes.[7]

Causality assessments indicated that a majority of the events had a probable (40%) or definite (37.5%) association with the device involved, while 20% were classified as possible. Only one event (2.5%) was deemed unrelated, reinforcing the clinical relevance of these reports in ongoing device safety evaluations.

In the accompanying cross-sectional survey, 121 healthcare professionals- including nurses, pharmacists, interns, and students- participated. Most respondents were female (65.3%), and nurses represented the largest professional category (51.2%). While awareness of MvPI was relatively high (78.5%), only 34.7% had previously reported a device-related adverse event. Furthermore, although 63.6% were familiar with the reporting process, 51.2% had not received any formal training on materiovigilance, highlighting a gap between awareness and practice. A large proportion of respondents (66.9%) strongly agreed, and 31.4% agreed that adverse event reporting contributes to patient safety. Nevertheless, several barriers were identified- 38.8% feared legal consequences, and 44.6% perceived the reporting process as time-consuming. Additionally, 38% of participants reported challenges in accessing the MvPI reporting form, and 71.9% emphasized the need for anonymity in the reporting process.

The most frequently cited barrier to reporting was a lack of awareness about how to report (19%). Participants recommended multiple strategies to improve reporting, including regular training sessions (17.3%), simplified reporting mechanisms, feedback systems, and assurance of confidentiality. These recommendations align with previous research advocating for structured training and

robust surveillance frameworks to enhance reporting culture and ensure patient safety.

Limitations

This study has several limitations that must be acknowledged. Firstly, the sample size was relatively small, involving only 40 adverse event reports and 121 healthcare professionals, which may limit the generalizability of the findings. The data were collected from a single center or a limited geographic area, which may not be representative of the broader healthcare system or national trends in medical device usage and adverse event reporting. Secondly, the clinical context of many events was limited. In several cases, there was insufficient documentation to conclusively determine the exact cause of the event, especially in multi-factorial scenarios involving comorbidities or surgical complications. Thirdly, Participants may have over- or under-reported their knowledge, attitudes, or practices due to social desirability or recall bias. Despite these limitations, the study highlights critical gaps in awareness, training, and system-level support in medical device safety reporting. It provides a foundational understanding that can inform future national strategies aimed at strengthening the MvPI framework and improving patient safety.

CONCLUSION

This study highlights the significance of systematic monitoring and reporting of medical device-associated adverse events (MDAEs) to enhance patient safety and strengthen the materiovigilance framework in India. The analysis of 40 MDAE cases revealed that higher-risk devices (Class C) were significantly associated with serious adverse outcomes, with causality assessments indicating that the majority of these events were either probable or related to the medical devices in use. Furthermore, the cross-sectional survey involving 121 healthcare professionals demonstrated a high level of awareness regarding the Materiovigilance Programme of India (MvPI), yet actual reporting practices remained suboptimal. Notably, only one-third of respondents had previously reported an adverse event, and over half had not received any formal training in materiovigilance. Barriers such as lack of knowledge on how to report, concerns about legal repercussions, limited accessibility to reporting tools, and time constraints were prominent. Despite these challenges, participants expressed a strong belief in the importance of adverse event reporting for patient safety, and showed a positive attitude towards future engagement if appropriate training and support mechanisms are implemented. These findings underscore the need for targeted interventions, including regular educational workshops, streamlined reporting processes, and institutional encouragement to foster a culture of safety and accountability in clinical practice. Strengthening the MvPI infrastructure with emphasis on user-friendly tools, confidentiality assurance, and feedback systems will be essential in promoting a proactive approach to medical device safety. This study contributes to the growing body of evidence advocating for a robust post-market surveillance system and calls for national-level strategies to ensure safe and effective use of medical devices across healthcare settings.

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