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Original Article

Pattern and occurrence of medical device adverse events at a medical device monitoring centre in Central India: A three-year surveillance study

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ABSTRACT

Background: *Various horrific adverse events have been reported due to malfunctioning of medical devices. To safeguard the health of Indian population and to promote the patient safety and welfare of Indian population by monitoring adverse events related to medical devices, Ministry of Health & Family Welfare (MOHFW) has started Materiovigilance program of India (MvPI) in July 2015. Under the program of Materiovigilance (MvPI), nationwide medical device monitoring centers (MDMC) have been established. This study was conducted to analyze and present the occurrence and severity of spontaneous MDAE reports registered at an MDMC in Central India.* ***Methods:*** *This non-interventional study was a part of MvPI and presents the data collected from one of the MDMC under MvPI. All MDAE reports received from the hospital of AIIMS Bhopal between August 2019 and September 2022 at the MDMC –AIIMS Bhopal in Central India; were included in the study. The medical device adverse event (MDAE) reporting form, recommended by the IPC Ghaziabad, was used as the data collection tool. The personal identification variables were masked before analyses, to maintain full confidentiality.* ***Results:*** *Spontaneous MDAEs reports were collected and analyzed during 3 years at the MDMC. A total of 309 MDAE reports were generated from 151 medical devices and 291 patients. Out of total 309 MDAE, 88% were non serious in nature, 10% were serious in nature & 2% were near miss events. Causality was conducted as per WHO adapted UMC criteria. Maximum MDAEs came in probable category (58%) followed by possible (25%), unlikely (09%), not related (04%) & un-assessable (04%). Maximum reporting was done from covid wards & ICUs, followed by obstetrics & gynecology, orthopedics & radiology department.*

Conclusion: *Allergic contact dermatitis from sanitizers and PPE kits was the most commonly reported MDAE, followed by invalid urine pregnancy test kits, orthopedic implant related adverse events & intravenous infusion pump. Underreporting of MDAEs at our MDMC is evident and a major factor for the pause in performing severity and causality assessment. To deal with the problem of under-reporting, we suggest continuous sensitization and training program for HCPs. We also suggest involving all stakeholders in MvPI, including government hospitals, private hospitals, and AYUSH hospitals. All the stakeholders should be assured that reporting MDAEs has no legal implications.*

Keywords: *Medical device adverse events, Materiovigilance, medical device, pattern*

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INTRODUCTION

In the past, various serious events have happened due to malfunction of medical devices like infant burn due to overheating of pediatric incubators, heavy metal poisoning and metallosis due to orthopedic implants, fire in intensive

care units due to malfunctioning of ventilators etc. To safeguard the health of Indian population and to promote the patient safety and welfare of Indian population by monitoring adverse events related to medical devices, Ministry of Health & Family Welfare (MOHFW) has started Materiovigilance program of India (MvPI) in July 2015. All medical devices carry certain level of risk. Materiovigilance[1,2] means close monitoring of any undesirable performance or characteristics fluctuations of a medical device by means of a system which is capable of identifying, collecting, reporting with estimate of undesirable occurrences and reacting to them with field safety corrective actions or device recall during post - marketing phase of a medical device. The term medical device[3,4] represents any instrument, apparatus, implant, in vitro reagent, or software intended for disease diagnosis or treatment in humans. In addition to creating database on medical device adverse event, Materiovigilance programme will give insight to reduce reoccurrence of adverse events related to medical device elsewhere thereby improving medical device quality by and large. For Materiovigilance Programme of India (MvPI), Indian Pharmacopoeia Commission (IPC) Ghaziabad is a National Coordination Centre (NCC). Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), Thiruvananthapuram is working as National Collaboration Centre. National Health System Resource Centre (NHSRC), New Delhi, is working as technical support partner and Central Drugs Standards Control Organization (CDSCO), New Delhi, is a national regulatory agency. Under MvPI, various medical device adverse event monitoring centres (MDMC) have been established in different medical institutes of India, which collect, report & analyze medical device adverse events (MDAEs) from attached hospital. These reports are further sent to IPC Ghaziabad. The study was conducted to analyze and present the occurrence and severity of spontaneous MDAE reports registered at an MDMC in Central India.

METHODS

Study Design & settings

This non-interventional study was a part of MvPI and presents the data collected from one of the MDMC under MvPI. All MDAE reports received from the hospital of AIIMS Bhopal between July 2019 and September 2022 at the MDMC –AIIMS Bhopal in Central India; were included in the study. The institute is recognized as an MDMC since August 2019.

Data collection considerations and analysis

The medical device adverse event (MDAE) reporting form, recommended by the IPC Ghaziabad, was used as the data collection tool. A dedicated form, recommended by IPC Ghaziabad for reporting of adverse events related to PPE kit, was used. The suspected MDAE were spontaneously reported by the healthcare professionals (HCPs), patients or patient's relatives to our MDMC. All MDAEs reported between August 2019 and September 2022 was included in the study. The data were recorded and entered in microsoft excel sheet. The data were analyzed anonymously to maintain full confidentiality. The analyses were conducted based on patient demographic parameters, details of medical device, details of MDAEs, medical specialty involved & causality analysis. Appropriate descriptive statistics were used to analyze the quantitative data. The causality of the reported MDAE was categorized into not related, unlikely, possible, probable, causal relationship and unassessable. Causality categories were adopted from European Directives 90/385/EEC and 93/42/EEC and WHO-UMC system for standardized case causality assessment using the WHO causality assessment scale[5,6].This scale is used for the assessment of the relationship between a medical device and the occurrence of a MDAE. A serious reaction[7] was characterized as a fatal, life-threatening reaction that can prolong hospitalization and cause a significant persistent disability that might result in a congenital anomaly and require an intervention to prevent permanent damage or death. The personal identification variables were masked before analyses, to maintain full confidentiality. Since the results do not contain any personal information, taking consent from the patients was exempted. This was a non-interventional study where no influence was imposed on the treatment or medical care.

Statistical methods

The data were analyzed with excel and SPSS version 1.0.0.1406. The frequencies and percentage of categorical values were calculated. Sum, median, mean, ranges were calculated for the continuous numerical values. Percentages were rounded to the closest whole number. The independent t-test was used for the comparison of normally distributed and continuous variables. The $\chi 2$ test was used for comparison of categorical values, and p values.

RESULTS

Spontaneous MDAE reports were collected and analyzed during 3 years at the MDMC. A total of 309 MDAE reports were generated from 291 patients. The occurrence of MDAEs dominated among males 64% (618) than female patients (table 1). Maximum number of MDAEs were reported from the earning member of the group i.e., patients aged between 19 and 65 years (81%), and the overall mean age of the patients was 37.55 years. A peak of MDAE reports was attained in 2021 with 247 reports. The highest number of MDAEs were reported in the year 2021 (147), while the maximum number of serious MDAEs were reported in the year 2022 (55, figure 1). Out of total 309 MDAE, 31(10%) were serious, 268(88%) were non serious, 09 (02%) were near miss events.

Figure 2 summarizes the number of MDAE associated with various clinical departments. In total, 151 medical devices were implicated in causing the MDAEs, and sanitizers & personal protective equipment kit (PPE) were associated with the maximum number of the MDAEs (31%) followed by urine pregnancy test kits and intravenous infusion pumps.

Table 2 presents the types of MDAEs reported in various clinical specialties. The MDAEs of obstetrics & gynecology department (28%) were second most common followed by orthopedics, radiology and intensive care units. Invalid urine pregnancy test was most commonly reported MDAE from obstetrics & gynecology department. Implant related adverse events like surgical site infections, pus discharging sinus & implant failure were most commonly reported MDAE from orthopedics department. Fever, shivering & heaviness of head, after injection of contrast media were most commonly reported MDAE from radiology department. Intravenous infusion pump failure, patient monitor and ventilator malfunction were most commonly reported MDAEs from intensive care units. Allergic contact dermatitis after use of sanitizers, gloves & N-95 masks was most commonly reported MDAE from covid wards& ICU. Erroneous readings from BP instruments & glucometer were most commonly reported from medicine wards. Malfunction of hearing aids were most common MDAE from ENT department. Malfunctioning of DJ stents & PCNL guidewire were most commonly reported MDAE from urology department.

Table 4 shows the severity and causality assessment of reported ADRs. Ten percent of all reported MDAEs were serious, 88% were non serious & 2% were near miss events. Overall, 35 medical devices were associated with 41serious MDAE. Causality was conducted as per WHO adapted UMC criteria (Figure 4). Maximum MDAEs came in probable category (58%) followed by possible (23%), unlikely (09%), causal relationship (6%), not related (04%) & un-assessable (04%).

Table 1: Demographic parameters associated with MDAEs

Parameters value	Number of patient's n (%)	P
Total MDAEs	309	
Age groups		
0-18	30(10)	
19-65	247(79)	0.0001
>65	32(11)	
Gender		
Males	180 (62)	0.0001
Females	111(38)	

Table 2: Frequency of MDAEs based on medical devices

Medical devices	Number (%)	MDAEs
Sanitizers & PPE kits	74(24)	Allergic contact dermatitis, rashes
Urine pregnancy test kits	58(19)	Invalid test results
Intravenous infusion pump	55(18)	Administration errors, overdosing
Orthopedics implants	46(15)	Surgical site infections, pus discharging sinus, Allergic reactions, implant failure
Contrast media	43(14)	Fever, shivering, headache
BP Instruments	37(12)	False high readings, device malfunction
Glucometers	34(11)	False high readings, device malfunction
Infrared thermometers	12(5)	False high readings, device malfunction
Foleys catheters	5(2)	Failure of balloon inflation
Gypsona cast	5(2)	Too tight cast
Ventilators	11(10)	Unable to deliver tidal volume, Electric shock, power supply problem
DJ stent	02(01)	Forgotten DJ stent, renal & vesical calculus
PCNL guidewire	02(01)	Displaced guidewire
Hernia mesh	01(0.5)	Umbilical granuloma
Skin traction set	11(10)	Blisters
External fixator	05(02)	Non union
Cardiothoracic drainage	01(0.5)	Failure of self-test, sensor error
ICU monitors	29(10)	Sensor error, alarm error
Intrauterine devices	05(02)	Displacement, bleeding
IV cannulas	25(09)	Thrombophlebitis
IV set	19(07)	Leakage
Vacutainer	01(0.5)	Clotting of blood sample
Plaster cutter	5(02)	Product quality issue
Cautery	7(02)	Unable to cauterize for long duration
Pulse oximeter	6(02)	False reading, device malfunction
Hearing aids	03(01)	Fitting issues, abnormal sounds
Defibrillator	02(01)	Unable to deliver shock

Table 3: Causality assessment of MDAEs as per adapted from WHO UMC criteria

Levels of causality	Number (%)
Not related	15 (05%)
Unlikely	12 (04%
Possible	65 (23%)
Probable	186 (58%)
Causal relationship	15 (06%)
Unassessable	12 (04%)

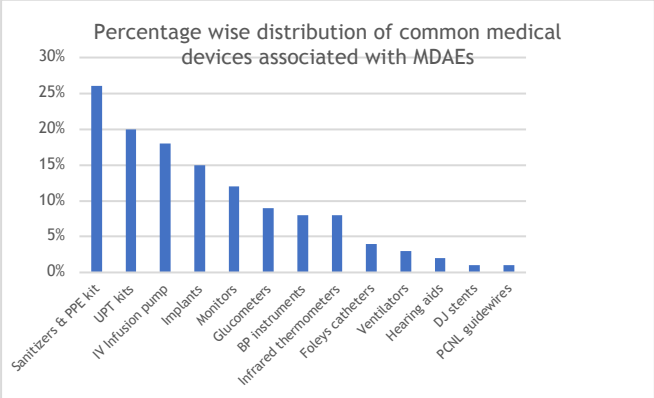

Figure 1: Distribution of common medical devices associated with MDAEs

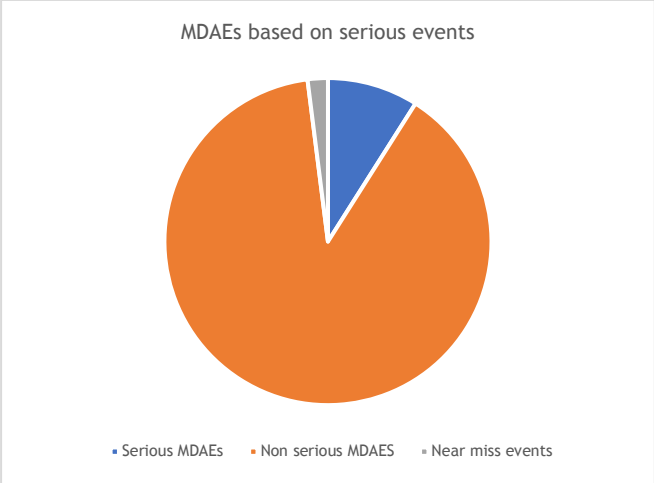

Figure 2: Types of MDAEs

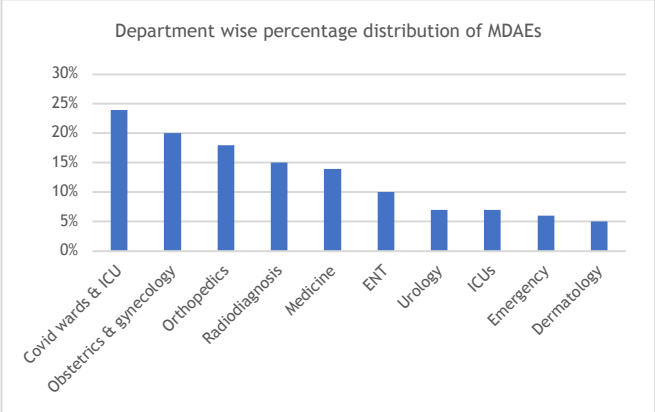

Figure 3: Distribution of MDAES based on department

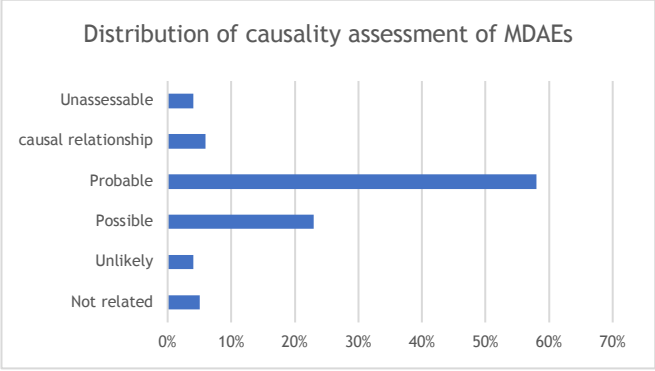

Figure 4: Distribution of causality assessment of MDAEs

DISCUSSION

There is a wide gap between the occurrence and reporting of MDAE in India and worldwide[8,9]. The present study illustrates the MDAEs reported at MDMC in Central India for the first time and presents a list of the causative medical devices for the burden of MDAEs. The study reported that sanitizers and PPE kits as the most commonly reported MDAEs from covid wards & ICU. Similar results were reported by Bryan et al[10] that COVID-19 related occupational dermatosis present occupational health challenges that affect many health care workers. This trend was due to occurrence of covid pandemic in year 2020 & 2021. After PPE kit related adverse events, invalid urine pregnancy test kits from obstetrics & gynecology department and implant related adverse events from orthopedics department were most common MDAEs.

Reporting of MDAEs is a collaborative study[11,12] conducted with the help of inputs from healthcare professionals or a person close to the patients. In our study, maximum numbers of MDAEs were reported in the year 2021. The maximum number of serious MDAEs was reported in 2022 & it was due to implant related adverse events due to prolongation of hospitalization (Figure 2). As per WHO, serious adverse events are those events, that has resulted in death, disability, congenital anomaly, prolongation of hospitalization, permanent disability or required intervention to prevent permanent impairment. A Near miss event is an unplanned event that did not result in injury, illness, or damage – but had the potential to do so.

Although the data collection started in August 2019, yet the numbers of reported MDAEs were lower for one and half a year. These low numbers might be due to lack of sensitization[13,14] of healthcare professionals & non availability of materiovigilance research associate for the year 2019 & 2020. After conduction of sensitization programs of healthcare professionals especially of nursing staff, the reporting increased in subsequent years. Since materiovigilance is relatively new concept, more sensitization[15,16] and training of healthcare professionals is required to improve reporting. At our center, sensitization program was conducted at regular intervals for different healthcare professionals. In our study, significantly more MDAEs were documented in the male patients than the female patients. However, the gender impact on the MDAEs occurrence cannot be explained here and might be an incidental finding and has no effect on the occurrence of reporting of the ADRs. In our study, the ADRs were predominantly reported in patients of age group between 19 and 65 years. This is because it is a wide age group range, and this is likely the major population that attends hospital more frequently. The results based on materiovigilance data are crucial to generate signals[17,18] and alerts. However, signals are generated based on a substantial number of reports after following the protocol. Yet, the frequencies of MDAEs reported by some of the devices in the present study are alarming. The medical device implicated for causing MDAEs shows that allergic contact dermatitis due to PPE

kits and sanitizers were maximally reported MDAE. This trend was due to covid pandemic[19,20] in 2020 & 2021. A dedicated MDAE form was developed from IPC Ghaziabad to report MDAE due to PPE kits. Implant related adverse events[21] were leading MDAEs in orthopedics department which prolonged hospitalization of patients & resulted in serious MDAEs. Various implants that were reported from orthopedic department were tibia locking plate, interlocking nail, femur intermedullary nail, 8-hole lateral end clavicle plate, dynamic hip screw, finer acetabular cup, proximal tibia locking plate. Joseph et al[22] concluded that metal hypersensitivity was as a potential etiology for implant failure. Metallosis[23] is a rare condition characterized by the deposition and build-up of metal debris in the soft tissues of the body associated with metal-on-metal (MOM) prosthetic devices. It can present with local/systemic symptoms and signs due to a chronic inflammatory host response. Malfunctioning of hearing aids[24,25] was most common MDAE from ENT department but that was mostly non serious. Similar results were reported from Vinaya & Harvey et al.[24, 25] In our study, malfunctioning of DJ stents, PCNL guidewire & Foleys balloon were reported from urology department, some of which were serious in nature. Forgotten DJ stent[26] is still a common problem in developing world, and it also brings lot of morbidity and financial burden to patient. This also increases strain on resources and infrastructure which is already limited in developing countries. In most of patients, endourological procedure is required for management of such cases with few requiring open surgery. Proper education and counseling of patients and relatives before and after procedure and maintaining stent register may help in reducing incidence of forgotten DJ stent. Malfunctioning of ventilators from covid ICU was also serious MDAE. Invalid urine pregnancy test and intrauterine contraceptive devices (IUCD) related adverse events were commonly reported MDAE from obstetrics & gynecology department. No common device class could be implicated for causing serious MDAE.

CONCLUSION

As per best of our knowledge, this is the first study from central India, which presents pattern of medical device adverse events (MDAEs) reported from medical device monitoring center (MDMC). Allergic contact dermatitis from sanitizers and PPE kits was the most commonly reported MDAE. This trend was due to excessive usage of sanitizers and PPE kits during covid pandemic. Implant related adverse events were commonly reported MDAE from orthopedic department. Underreporting[27] of MDAEs at our MDMC is evident and a major factor for the pause in performing severity and causality assessment. Causality assessment was conducted in majority of reported MDAEs; however, root cause analysis could not be conducted in majority of MDAEs due to lack of patient follow ups. In some of reported MDAEs patient details could not be retrieved due to lack of patient follow up. To deal with the problem of under-reporting, we suggest continuous sensitization and training program for HCPs. We also suggest to involve all stakeholders in MvPI, including district hospitals, private hospitals and AYUSH hospitals. Therefore, we propose to develop a model with a strategy to provide feedback and knowledge to improve MDAE reporting. Furthermore, providing feedback to the prescribers and sensitizing them about the MDAEs will be an encouragement for reporting. All the stakeholders should be assured that reporting MDAEs has no legal implications.

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