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MATERIOVIGILANCE : AN EMERGING DISCIPLINE

Clinical Research

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ABSTRACT

Medical devices have been in use in healthcare all over the world since long ago. With advancements in technologies, the number and variety of medical devices used in clinical setup are rising day by day. Similarly, there has been an increase in the number of adverse events associated with medical devices. All over the world various approaches are being developed to quantify, evaluate and prevent these events along with attempts to improve the quality of medical devices. The ultimate aim has always been to improve patient safety. Materiovigilance Programme of India launched on by DCGI at Indian Pharmacopoeia Commission in Ghaziabad in 2015. The purpose of this programme is to monitor medical device associated adverse events (MDAE). In United states of America such a programme has started under the name Medical Device Reporting (MDR). Similarly, many developed countries like France, Australia and United Kingdom have also come up with their own programmes.

KEYWORDS

Materiovigilance, MvPI, Medical devices.

Introduction

The word materiovigilance is a combination of two words – 'materio' which means 'the material from which a thing is or can be made' and 'vigilance' which means 'more careful attention, especially in order to notice possible danger'. Hence the term materiovigilance is defined as "close monitoring of any undesirable occurrence resulting from a medical device by means of having a system in place which comprises identifying, collecting, reporting, and estimating undesirable occurrences and reacting to them, or safety corrective actions after their post-marketing phase" [1]. Any instrument, apparatus, machine, appliance, implant, reagent for in-vitro use, software or other articles to be used for humans for specific medical purposes is termed as medical device. Examples of medical devices include a wide variety of devices, like thermometer which are used very commonly to advanced medical ventilators used in critical care units. Indeed, present medical care is tremendously dependent on medical devices for prevention, diagnosis, treatment and investigation of diseases and injuries.

The use of medical devices may also lead to occurrence of some adverse events, for e.g.- incorrect test results by a glucometer, malfunctioning of an infusion pump leading to injury to the patient, a malfunctioning automated external defibrillator device (AED) leading to electrical burns to a patient or a health service provider etc.

Thus, there arises a need for a system to be in place so that such events can be reported and noted by an agency so that it helps in identifying the risks associated with medical devices and to withdraw those medical devices from the market and to eliminate the dangers of such adverse events occurring in future. And that void has been filled by the concept of Materiovigilance.

Materiovigilance Programme of India (MvPI)

The Drugs and Cosmetic Act, 1940 lists rules governing standards and requirements for manufacturing of medical devices under Schedule R-1 and Schedule M-III, respectively. These rules are related to quality, manufacture, distribution, sale, import and export of medical devices in India.

The Materiovigilance Programme of India [2] was approved by the Ministry of Health and family Welfare on 10/02/2015 and it was launched on 06/07/2015 by DCGI at Indian Pharmacopoeia Commission in Ghaziabad. It was decided that Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), Thiruvananthapuram, will be National Collaborating Centre; National Health System Resource Centre (NHSRC), New Delhi, be Technical support partner, and Central Drugs Standards Control Organisation (CDSCO), New Delhi, will function as regulator.

The purpose of this programme is to monitor medical device associated adverse events (MDAE), and to create awareness in health-care professionals regarding the value of reporting these adverse events and also to keep a check on the risk-benefit ratio of use of medical devices. The programme also aims at providing independent, evidence-based data and directions on the safety of medical devices and to convey the findings to the stakeholders.

The stakeholders involved are –

1. Professional staff at IPC, SCTIMST, NHSRC and all such institutions that would serve as stakeholders of the programme.
2. Representatives of Medical Device Monitoring Centre.
3. Staff and consultants in CDSCO
4. Policy makers at all levels of healthcare, particularly those concerned with Medical Device policy.
5. Under MvPI clinicians, biomedical engineers, clinical engineers, hospital technology managers, pharmacists, nurses, technicians can report medical device adverse events. Medical device manufacturers/CDSCO-notified medical device manufacturers/ medical devices' importers-traders can also report adverse events specific to their product to the National Coordinating Centre.
6. Medical Technologists and Innovators.

The adverse events have been classified according to severity into – 1) Death of a patient, user of the device or other person, 2) Serious injury to a patient, user or other person, and 3) No Death or No Serious injury occurred but the event might lead to death or serious injury of a patient, user or other person, if the event recurs.

The reporting of the medical device associated adverse events is to be done through the form prescribed by MvPI [3]. This form can be downloaded from www.ipc.gov.in. The reporting can be done by clinicians, biomedical engineers, clinical engineers, hospital technology managers, pharmacists, nurses and technicians. Medical device manufacturers can also report adverse events specific for their product. A toll-free helpline number – 1800-180-3024 has also been made available and can be used to get assistance for reporting the adverse events.

The major utilization of Materiovigilance is-

1. Prevention of injuries and complications.
2. Improvement in design and efficiency of medical devices.
3. Reporting and investigation of medical device associated adverse events.
4. Implementation of corrective actions to prevent adverse events in future.

In our institute, BPS GMC for Women, Khanpur Kalan in Sonipat (Haryana) materiovigilance programme is being carried out along with pharmacovigilance programme. Some of medical device related adverse events have been reported. Two cases of surgical glove related rashes over hands and three cases of intravenous cannula induced thrombophlebitis have been reported.

Materiovigilance in other countries

In United States of America, U.S. Food and Drug Administration (USFDA) has a similar programme known as Medical Device Reporting (MDR). In this programme FDA, has made it mandatory for the manufacturers, health facilities using medical devices, and importers to report medical device related adverse events which is called as Mandatory Medical Device Reporting. The second category is of Voluntary Medical Device Reporting which consists of healthcare professionals, patients, caregivers and consumers, who are encouraged by the FDA to submit reports of adverse events voluntarily. In France, there is a national surveillance commission for medical devices ("Commission de Matériovigilance"). In Australia, there is Therapeutic Goods Administration (TGA) which functions under the Department of Health of the Australian government. In United Kingdom, there is Medicines and Healthcare Products Regulatory Agency (MHRA) [4].

Discussion

In a study done in San Francisco, over a period of 35 months, the autopsy findings revealed that out of 517 sudden cardiac deaths that occurred during that period 11 deaths occurred due to malfunction of cardiac implantable electronic devices (CIEDs) [5].

It has been reported that a company named, Intuitive Devices, which manufactures Robotic surgery devices – da Vinci – has become a target of 52 lawsuits against it since its FDA approval in 2000, due to malfunction in their robotic surgery devices [6].

On 28 November 2017, the Therapeutics and Goods Administration (TGA) Australia decided to ban pelvic mesh implants, after repeated reports and studies indicating increased risk of injury and death in women receiving pelvic mesh implants for stress incontinence [7].

Recently, it has been reported that the Central Drug Standards Control Organization (CDSCO), has proposed changes in the existing law to introduce a compensation provision for approved drugs and medical devices that have an adverse impact on a patient [8].

Conclusion

Various medical devices are used by physicians to assist them in curing the patients and saving lives. They are in no way supposed to do any harm to the patients. Nowadays it has become a trend to blame the treating doctor in case of any bad outcome while treating a patient. It is very difficult for a common man to understand the complications of medical science, but blaming the doctor has always been easy. It is true that, a doctor always treat his patient with good intention, but if any adverse event occurs, fault may lie somewhere else, for example in the medicine or in the medical device. Hence, to find and to investigate those errors we require Pharmacovigilance along with Materiovigilance. The most important aim is to prevent those errors from reoccurring.

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