Indian Heart Journal 72 (2020) 316–318

Contents lists available at ScienceDirect

Indian Heart Journal

journal homepage: www.elsevier.com/locate/ihj

Opinion Paper

Materiovigilance Programme of India: A scheme to assure cardiovascular devices safety surveillance

V. Kalaiselvan [a, *], Santanu Kumar Tripathi [b], Jai Prakash [a]

[a] Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, Government of India, Sector 23, Raj Nagar, Ghaziabad, UP, 201002, India
[b] Department of Clinical and Experimental Pharmacology, School of Tropical Medicine, Kolkata, 700073, India

ARTICLE INFO

Article history:
Received 14 May 2020
Accepted 21 June 2020
Available online 1 July 2020

Keywords:
Materiovigilance
Medical devices
Adverse events
Cardiovascular devices

ABSTRACT

The Materiovigilance Programme of India (MvPI) has been implemented to ensure the safety of medical devices including cardiovascular devices (MD-CVD). This article describes the role of MvPI surveillance system that comprehensively collects, collates and analyses the adverse events associated with MD-CVD and also its supplementing role to the Central Drugs Standard Control Organization for taking regulatory decision to reduce the health burden on account of adverse events due to medical devices to the patients based on the evidence based data. This article is expected to stimulate ethical reporting of adverse events due to MD-CVD at MvPI.

The Ministry of Health & Family Welfare (MoHFW), Government of India has notified Medical Devices Rules (MDR) 2017 with the aim to bring in the highest degree of professionalism in regulating medical devices. As per the MDR, the devices are classified, based on degree of risk associated as Class A (low risk), Class B (low moderate risk), Class C (moderate high risk) and Class D (high risk). The cardiovascular devices such as drug eluting stent, heart valve, bioresorbable vascular scaffold system, over-the wire-thrombectomy set, cardiac pacemaker, cardiac portable monitor and others are classified under D Category. The manufacturers of medical devices including that of cardiovascular related shall be required to meet risk proportionate regulatory requirements that have been specified in the Rules and are based on best international practices.[1] As per the MDR, G.S.R. 78, Chapter 4, Section 26 (ii) the adverse events reporting associated with medical devices to the relevant authority is mandatory; the License Holder shall inform the State Licensing Authority or Central Licensing Authority, as the case may be, of the occurrence of any suspected unexpected serious adverse events and take necessary action thereon including any recall within 15 days of such event coming to the notice of License Holder.

Although, medical devices adverse events reporting are compiled by law in many countries, the reporting to the authority and its surveillance system are a grave concern.[2–5] Therefore, besides the MDR, in order to promote the culture of adverse events reporting, the MoHFW, Government of India had approved the commencement of Materiovigilance Programme of India (MvPI) in order to monitor and assure the safety of medical devices used in Indian population in 2015.[6] The Indian Pharmacopoeia Commission (IPC) under the MHFW functions as National Coordination Centre (NCC) for MvPI since 2018. The MvPI aims to collect, collate and analyze the voluntarily reported adverse events associated with medical devices and thus arriving at meaningful or evidence based information that is being recommended to the regulatory authority and general public for promoting the safe use of medical devices including cardiovascular devices (Fig. 1).

The aim of this article is to familiarize the readers with the scheme and process for adverse events reporting for cardiac devices currently in India. In order to facilitate adverse events reporting from the region, a structured programmatic approach has been made by recognizing medical colleges/hospitals/other related institutions as Medical Devices Adverse Events Monitoring Centres (MDMCs) across the country. The MDMCs are primarily responsible for monitoring and reporting the adverse events within their hospital to MvPI. The concerned centre assigns these responsibilities to a Clinician or Pharmacologist or Biomedical engineer or other healthcare professionals as a coordinator or deputy coordinator. The MDMCs are also responsible for education and advocacy on promoting the concept of MvPI as well as creating a culture of adverse events reporting. A customized medical devices adverse events reporting from is readily available at the MDMCs. This form has been featured with the adequate information related to the event to be captured (Table 1). In order to facilitate the seamless assessment of the reported event the

* Corresponding author. Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, Government of India, Sector 23, Raj Nagar, Ghaziabad, UP, 201002, India.
E-mail address: vivekarts@gmail.com (V. Kalaiselvan).

https://doi.org/10.1016/j.ihj.2020.06.009

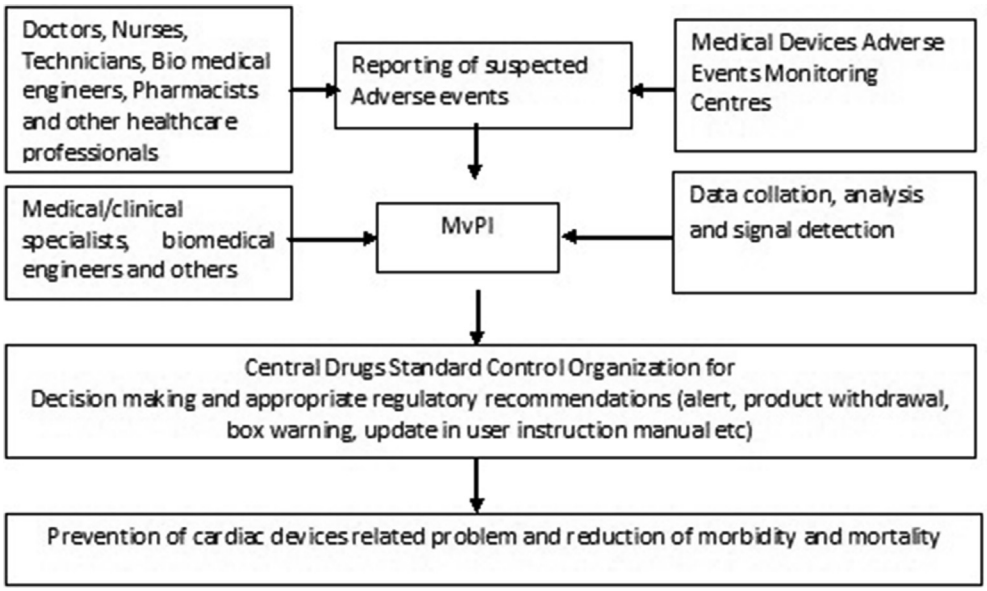

Fig. 1. Process flow of Medical Devices-Cardiac Devices adverse events reporting system in Materiovigilance Programme of India (MvPI).

Table 1
Suspected adverse events associated with the use of cardiac devices reporting – requirement of minimum information for root cause analysis.

S. No	Type/category of Information	Details
1	General information	Date of report, type of report (initial/follow up/final/trend)
2	Reporter details	Type of reporter (manufacturer/importer/healthcare professionals or others) and reporter contact information
3	Device category	Device type (therapeutic/diagnostic/preventive/others), invasive/non invasive, single use/reusable, sterile/non sterile and others
4	Device details	License number, batch/model, manufacturing date, expiry date and others
5	Event description	Event date, date of implant, serious/non serious, description of the event, device operator and others
6	Patient information	Patient initial, age, gender, weight, relevant medical history, patient outcomes (recovered/not recovered) and others
7	Causality assessment	Investigation action taken, root cause of problem and others
8	Manufacturer's investigation and action taken	Devise risk analysis report, corrective/preventive action taken, device history review and others

minimum required information such as a reportable adverse event, identifiable patient and reporter, product exposure, device category/model should be available.

The MvPI also empowers the hospitals/healthcare professionals other than the MDMCs also to participate and report the adverse events through the customized paper based reporting form which is available on www.ipc.gov.in. As consumers or patients are important stakeholders of MvPI, they are encouraged to report adverse events (if any) via toll free helpline i.e. 1800 180 3024. In addition, medical devices manufacturer, importers etc are encouraged to report medical device related adverse events or problems to MvPI. The medical devices – cardiac devices manufacturers are also required to inform MvPI about their devices alert/recall/field safety corrective action etc; this will help MvPI in base line study and prompt decision making. The MvPI has engaged in providing continuous education and advocacy to the healthcare providers and industry as the medical devices – cardiac devices adverse events reporting differ from that of drugs; in cardiac devices reporting is required for incidents as well in which the device might have associated with serious adverse events including death due to malfunction, lack of quality, breakage etc At the MvPI, each adverse event case report is evaluated for the adequacy and accuracy of the information, the temporal association of the product and the event, confounding factors such as patient co morbidities, concomitant medication etc. If, on completion of review of all information available with the adverse event report, the safety signals are confirmed, then further course of actions to recommending the National Regulatory Authority i.e. Central Drugs Standard Control Organization (CDSCO) for appropriate regulatory action in the interest of patient safety is taken.

The MvPI, with its few years experience encourages receiving the adverse events associated with medical devices; including cardiac stents. The MvPI also indented to develop online reporting system and data management to manage medical devices – cardiac devices safety in order to ensure seamless reporting. Further, this article is to encourage consumers, clinicians and other healthcare providers to participate in ethical reporting of adverse events associated with cardiac devices and discuss device related problems with MvPI if required and effective communication of information to the end uses i.e. patients. The existing MvPI surveillance system is expected to stimulate healthcare professionals and consumers to report cardiovascular device related adverse event and on voluntary basis and reduce adverse event's burden to the patients.

Conflict of interest

There is no conflict of interest.

References

1. www https://pib.gov.in/newsite/printrelease.aspx?relid=157955.

2. Nobuhiro H, Kensuke I, Yutaka M, Yuki A. Reporting of cardiovascular medical device adverse events to pharmaceuticals and medical devices agency. *Japan EBioMed*. 2015;2(9):1211–1216.
3. James WS, Rita FR. Leading the call for reform of medical device safety surveillance. *JAMA Intern Med*. 2020;180(2):179–180.
4. Hefflin BJ, Gross TP, Schroeder TJ. Estimates of medical device – associated adverse events from emergency departments. *Am J Prev Med*. 2004;27:246–253.
5. Craig A, O'Meley Carter P. The need for greater reporting of medical devices incidents. *EMJ Innov*. 2019;3:56–63.
6. Shatrunajay S, Madhur G, Sabitri P, et al. Implementation of adverse event reporting for medical devices, India. *Bull World Health Organ*. 2020;98:206–211. https://doi.org/10.2471/BLT.19.232785.