Intraocular devices associated adverse events reporting system in India

Development and use of medical devices (MDs) have always been high but recently there has been a marked increase in the use of devices in ophthalmology. Although before entering the Indian market, drugs go through an extensive evaluation and monitoring process, there are constant reports of adverse events noticed as the duration of the availability of the drug increases and a large number of patients get exposed to the drug. While there has been a robust system for the documentation of adverse events related to marketed ophthalmic drugs, there was no documentation of the side effects and problems related to MDs in ophthalmology.[1]

In the last five years, there has been a growing recognition of the magnitude of the problem and increasing focus on the quality and safety of MDs in India. Also, there has been a policy level development as the Medical Device Rules, 2017 ("MDR"), issued under the Drugs and Cosmetics Act, 1940 are in line with the Global Harmonization Task Force framework and confirm to best international practices. Under the MDR, intraocular devices (IODs) also have been notified as drugs and regulated by the Central Drugs Standard Control Organization (CDSCO). As per the risk-based classification of MD under MDR, the IODs are classified under C category, i.e., moderate-to-high risk [Table 1]. To generate adverse events (associated with MDs – IODs) database for assessing the benefit-risk ratio and then provide MDs safety information to the public and CDSCO on MDs, the Materiovigilance Programme of India (MvPI) has been launched by the Ministry of Health and Family Welfare, Government of India. The Indian Pharmacopoeia Commission under the Ministry of Health and Family Welfare functions as a National Coordination Centre for MvPI and is responsible for developing tools and systems for the MDs –IODs and others for adverse events reporting, assessment, and safety communication for assuring patients safety.[2] The purpose of MvPI is to:

- Create a nation-wide system for patient safety monitoring
- Analyze the benefit-risk ratio of medical devices
- Generate evidence-based information on the safety of medical devices
- Support CDSCO in the decision-making process on the use of medical devices
- Communicate the safety information on the use of MDs to various stakeholders to minimize the risk
- Emerge as a national center of excellence for Materiovigilance activities
- Collaborate with other healthcare organizations for the exchange of information and data management.

Table 1: Risk-based classification of certain MDs as per MDR 2017

Class	Risk level	Devices
A	Low risk	Thermometers, Tongue depressors, surgical dressings, swabs, and others
B	Low-moderate risk	Hypodermic Needles, Suction equipment, Hematology Reagents kit, and others
C	Moderate-high risk	Intraocular lenses, Lung ventilator, Bone fixation plate, and others
D	High risk	Cardiac stents, Implantable defibrillator, Cochlear Implants, and others

The adverse event of MDs – IODs reporting to MvPI by the healthcare professionals, MDs manufacturers/importers, consumers, and others is entirely voluntary and is progressively increasing in recent years. In addition to voluntary reporting to MvPI, there is mandatory reporting for the MDs manufacturers/importers/others that receive a serious report and must submit it to the CDSCO. The CDSCO takes necessary regulatory decisions over the safety of MDs by examining the gravity of the information received from mandatory reporting as well as reports received from MvPI.

Even though currently over 90% of cataract surgeries involve implantation of Intra Ocular Lens (IOLs), the adverse events associated with IOLs are mainly reported from the west.[3-5] However, adverse events of IOLs are less or not reported in the Indian population as safety concerns, possibly as the stakeholders might not be aware of the reporting system and its significance. Some of the key issues related to IOLs are poor visual outcomes due to halos, glare, starbursts, fracture of the lens haptic noticed before or during insertion, failure of the lens to open, injector failure or cracks or breaks in the lens. Similarly, approximately one in every 2500 daily disposable contact lens users and one in every 500 extended wear soft lens users develop presumed microbial *Keratitis* every year[6] but such information is unavailable from India. Glaucoma drainage devices are increasingly finding acceptance among glaucoma specialists as an alternative to trabeculectomy in certain conditions. It was due to documentation of adverse events that some devices have been modified or even withdrawn. As the adverse event reports related to a device accumulate with time, essential investigations about the product can be initiated, which may result in modifications to the product or its withdrawal from the market. This will not only help in added safety for the patients but also help in the development and research of ophthalmic devices. Unfortunately, due to the lack of reporting of device-related complications, there is a failure to identify potential problems and thus expose patients to unnecessary risks.

The aim of this communication is to familiarize the healthcare professionals particularly ophthalmologists and eye researchers with the significance and process of adverse events reporting for Ocular devices in MvPI.

What is Included Under Medical Devices in Ophthalmology?

Every piece of equipment that is used for the diagnosis, for monitoring, and for treatment of disease is considered a medical device. The most commonly used ophthalmic MDs are contact lenses and lens care products, intraocular lenses, glaucoma drainage devices, keratoprostheses, capsule tensions rings, artificial iris implants, orbital implants, and prostheses. Similarly, any diagnostic equipment including slit lamps, operating microscopes, tonometers, fundus cameras, surgical instruments, and low vision aids would also be included.

Any adverse event that occurs with the use of a medical device needs to be reported. Reasons for adverse events involving devices may be:

- Related to the design or manufacturing problems,
- Inadequate servicing and maintenance,
- Unsuitable storage conditions,
- Poor user instructions or training resulting in incorrect user practice,
- Off-label use of a device,
- Local modifications etc.

Channels for IODs Adverse Events Reporting at MvPI

Adverse events related to IODs can be reported directly by the ophthalmologist or other healthcare professionals and patients to the Medical Devices Adverse Events Monitoring Centers (those are public or private or hospitals/research institutions) by using the customized paper-based reporting form. The stakeholders are expected to provide certain minimum information on suspected adverse events to validate and assess the report [Table 2].

In addition, to foster seamless reporting, a helpline (toll free number 1800 180 3024) facility is available at IPC which also receives the adverse events reported from healthcare professionals and patients.

What to Report?

The reporters must ensure that essential information is entered in the reporting form such as the type of adverse event, identifiable patient and reporter, product exposure and device category/model. The other important information to be given is whether the MDs – IODs adverse events are unexpected or an inappropriate medical occurrence, has resulted in an unintended disease or injury or the patient, users or other persons have developed inconvenient clinical signs (including abnormal laboratory findings), and whether or not they are related to the devices. Also, causes of incidents involving devices such as design or manufacturing problems, inadequate service and maintenance, storage problems, off-label use of device, etc., should be reported. The healthcare professionals are encouraged to report serious or nonserious, known or unknown frequent or rare and all types of suspected adverse events associated with MDs – IODs irrespective of an established causal relationship between the event and MD.

What Happens to the Adverse Events Reports at MvPI?

At the MvPI, the adverse events received from hospitals, healthcare professionals, and manufacturers are documented. The MvPI screens and assesses all adverse event reports received and prioritizes those serious in nature. In each adverse event report, the accuracy and adequacy of information, the temporal relationship between the device and event, and confounding factors such as the patient's clinical condition and concomitant medication are evaluated. This helps to determine whether the adverse event may be related to the device and attributes for safety signals. These reports primarily serve as evidence-based information for regulatory decisions such as field safety corrective action or recall related to the potential for harm of IOD/others, update in instructions for the user manual, and warning (if necessary). Also, such reports are supplemented with the process of benefit-risk assessment of respective medical devices. The findings arrived after clinical/scientific assessment of the data are utilized for educational interventions or trainings to healthcare professionals for improving the safe use of medical devices. The suspected adverse events of IODs reporting and management at MvPI is given in Fig. 1.

Table 2: Suspected MDs-IOD's adverse events reporting - requirement of minimum information to root cause analysis

Type/category of Information	Details
General information	Date of the report, type of report (initial/follow up/final/trend)
Reporter details	Type of reporter (manufacturer/importer/ healthcare professionals and others) and reporter contact information
Device category	Device type (therapeutic/diagnostic/preventive/ others), invasive/non invasisve, single use/ reusable, sterile/non sterile and others
Device details	License number, batch/model, manufacturing date, expiry date, and others
Event description	Event date, date of implant, serious/ nonserious, description of the event and others
Patient information	Patient initial, age, gender, weight, relevant medical history, patient outcomes (recovered/ not recovered), and others

Devices Safety Communication

The safety information on MDs such as alert, recall, etc., will be communicated to the stakeholders via the MvPI—newsletter, website (www.ipc.gov.in), email, etc., besides communicating to CDSCO for necessary action at their end. The IODs safety information is crucial, as these results in important label change/ update of the product so that clinicians and others can take appropriate measures to prevent the reported adverse events.

Currently, complications associated with ophthalmic devices are not being documented or reported. There is a critical role of MvPI in monitoring the safety of all healthcare products and assuring the safety of ocular devices including IODs used in the Indian population. As the safety data may provide the initial signal of a safety concern, the stakeholders are urged to participate in the program by providing accurate and adequate adverse event data of IODs. A limitation in the current MvPI that there is no information on the number of users of specific IODs that can be used to calculate the proportion of the patients experiencing a similar type of adverse event, which needs to be addressed suitably over the years to come.

The suspected adverse events of IODs reporting to MvPI is completely voluntary in nature; patients and healthcare facilities are encouraged to report such events for promoting the healthcare delivery system. The identity of the patient and reporter shall be kept in strict confidence. Also reporting of adverse events of IODs does not bring any legal implications on the reporters in any manner.

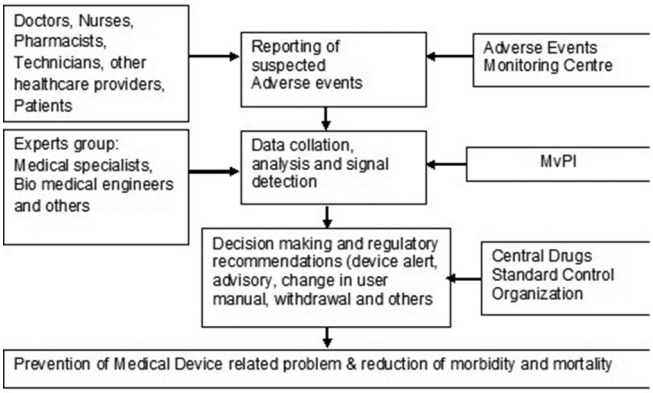

Figure 1: Medical Devices – Intra ocular devices adverse events reporting and management in MvPI

Conclusion

With a marked increase in the use of MDs in medicine and particularly in ophthalmology, the Materiovigilance program of India aims to collect, evaluate, and analyze data related to the safety of devices in a systematic manner. However, for its success, all the stakeholders associated with the manufacture, marketing, and use of medical devices must be made aware of the importance of generating safety data, documenting adverse events, and reporting to the MvPI. This will ensure that adequate measures can be instituted to protect the patients from untoward occurrences and risks associated with the use of medical devices and establish best practices and interventions for patient safety.

Vivekanandan Kalaiselvan, Rohit Saxena[1]

Materiovigilance Programme of India, Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India, Ghaziabad, Uttar Pradesh, [1]Dr R P Centre for Ophthalmic Sciences, All India Institute of Medical Sciences, New Delhi, India.
E-mail: vivekarts@gmail.com

References

1. Dubey A, Handu SS. Are we pharmacovigilant enough in ophthalmic practices? Indian J Ophthalmol 2013;61:226-9.
2. Shukla S, Gupta M, Pandit S, Thomson M, Shivhare A, Vivekanandan K, *et al*. Implementation of adverse event reporting for medical devices, India. Bull World Health Organ 2020;98:206-11.
3. Plager DA, Lynn MJ, Buckley EG, Wilson ME, Lambert SR. Complications in the first 5 years following cataract surgery in infants with and without intraocular lens implantation in the Infant Aphakia Treatment Study. Am J Ophthalmol 2014;158:892-8.
4. VISION2020 | THE RIGHT TO SIGHT INDIA.
5. Stein JD. Serious adverse events after cataract surgery. Curr Opin Ophthalmol 2012;23:219-25.
6. Stapleton F, Keay L, Jalbert I, Cole N. The epidemiology of contact lens related infiltrates. Optom Vis Sci 2007;84:257-72.

Access this article online

Quick Response Code:

Website: www.ijo.in

DOI: 10.4103/ijo.IJO_298_20

Cite this article as: Kalaiselvan V, Saxena R. Intraocular devices associated adverse events reporting system in India. Indian J Ophthalmol 2020;68:2343-5.

About the author

Vivekanandan Kalaiselvan

Dr Kalaiselvan has over 21 years of experience in the pharmaceutical sector in the realms of academic, pre-clinical and clinical research, pharmacovigilance and drugs standards setting. Currently, as Principal Scientific officer at the Indian Pharmacopoeia Commission, he is responsible to protect and promote quality standards, and safety and rational use of drugs. He is also working towards establishing Materiovigilance Programme of India to monitor the safety of medical devices. He has played a significant role to establish a robust system of Pharmacovigilance Programme of India,which has been recognized by the WHO as a collaborating centre. He has authored five books besides 85 articles in peer-reviewed journals. He has been the recipient of fellowship from DST and AICTE to pursue research projects.

Rohit Saxena

Prof. Rohit Saxena is on the faculty of Pediatric Ophthalmology, Strabismus and Neuro Ophthalmology at the Dr Rajendra Prasad Centre for Ophthalmic Sciences, All India Institute of Medical Sciences, New Delhi. He completed his medical and specialty training – MBBS, MD (Ophthalmology) and PhD from the All India Institute of Medical Sciences. He has numerous awards to his credit including the Best of Show Video at the American Academy of Ophthalmology 2019, Best Video SPOSI Annual Conference 2019, AIIMS Excellence Award 2018, Fan Favorite Video at the AAO 2016 and the AAO and APAO Achievement awards. He has over 180 indexed publications and has authored over 60 chapters in national and international books. He is the member of the Subject Expert Committee (Ophthalmology) constituted by the DCGI, is the principal investigator in many multicentric clinical trials and is involved in numerous path-breaking research projects.