Editorial

The need for pharmacovigilance in ophthalmic practice

Pharmacovigilance is monitoring the effects of drugs after they have been licensed for use to identify and evaluate previously unreported adverse drug reactions (ADRs). In totality, it deals with the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems.[1]

We often say that the eye is a window to the body. The myriad ophthalmic manifestations of systemic diseases encountered in clinical practice are a testament to that statement. Therefore, it is only logical that the various pharmacological agents used to treat systemic diseases, through diverse mechanisms – intended or otherwise can similarly have an effect on the eye as well. Conversely, it is equally plausible that a drug intended for ocular use can get absorbed into systemic circulation and result in deleterious adverse effects elsewhere in the body. The question is – how vigilant are we at detecting, treating, and reporting them?[1]

For example, sildenafil – a phosphodiesterase-5 inhibitor – was initially developed as a drug to treat angina. Soon, it evolved into the drug of choice for the treatment of erectile dysfunction. Over time, the drug was noted to selectively reduce pulmonary pressure and pulmonary vascular resistance in patients with pulmonary arterial hypertension.[2] Today, the drug is Food and Drug Administration (FDA) approved for the use in the treatment of pulmonary hypertension. Recently, there have been many reports linking the use of sildenafil and nonarteritic anterior ischemic optic neuropathy (NA-AION).[3] While subsequent studies have not yet established a clear causal relationship, FDA now requires all prescribing physicians to explain to their patients the low but possible risk of NA-AION.[4,5] Furthermore, it mentions that loss or decreased vision, whether painful or painless, demands urgent patient assessment and immediate cessation of phosphodiesterase type 5 inhibitor use.[6] This cascade of events occurred only through the efforts of clinicians engaged in diligent pharmacovigilance and proper reporting.

Similarly, topiramate – a drug used to treat migraine – has been reported to cause angle closure, whereas aripiprazole, an antipsychotic drug, has been known to cause transient myopia and even diplopia.[7,8] While informing peers in the form of case reports or other published material is important – it is equally important to intimate the drug regulatory authorities about such ADRs such that the issue can be investigated objectively. Once the causality is established, and the occurrence is established as a known ADR, it could help in other similar cases where the patient can avoid the trouble of going through detailed and exhaustive examinations and investigations.[1]

However, pharmacovigilance does not end there at reporting – pharmacovigilance is a continuing process that goes beyond the documentation of ADRs. Many drugs may perhaps be wrongly implicated or get a label of being a "dangerous" drug simply because of one reported an adverse event. Intravitreal use of antivascular endothelial growth factor (VEGF) was, at a point in time, considered to be directly responsible for thromboembolic events in patients who received these injections.[9] However, subsequent, large-scale studies have established that the incidence of vascular events in such patients was associated with older age rather than therapy received. Furthermore, the incidence rate of myocardial infarction, stroke, and death among patients treated with anti-VEGF was not significantly higher than the age-adjusted incidence rate of these events among the general population.[10,11]

To support the efforts of the medical fraternity to participate effectively, the Ministry of Health and Family Welfare via the Indian Pharmacopoeia Commission, has reached out and created a "Suspected Adverse Drug Reaction Form" which lays down the prescribed format for all clinicians to report ADRs to The National Coordination Centre - Pharmacovigilance Program of India. Often times, despite having observed unusual or rare ADRs, there seems to be inertia on the clinicians' part. In India, given the population, the amount of drugs prescribed and consumed by patients, it is evident that there is underreporting of ADRs primarily due to lack of knowledge and awareness about Pharmacovigilance Programme of India; lethargy, indifference, insecurity, and complacency among other things.[12] As elaborated by Kalasiselvan *et al*. in this issue, submission of an ADR report does not have any legal implication on the reporter and reporter details are maintained confidentially. This move facilitates smooth, standardized, and transparent reporting and enables the clinician to report ADRs in a systematic format without hassles.

Ophthalmology has changed drastically over the past two decades – intravitreal anti-VEGFs are now the first line of treatment in diabetic macular edema, and topical prostaglandin analogs are now routinely used as the front-line drugs in glaucoma. If we have upped our game in pharmacotherapy, why should our pharmacovigilance lag behind?

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