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Editorial Note

Black Triangle Drugs (▼) - An Outline

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Introduction

Each drugs undergoes clinical trial phase before introducing into pharmaceutical market. Generally clinical trials involve a small number of patients who take the medicine for a short period. During this phase, patients are carefully selected and followed up very closely under controlled conditions. These initial trials will report only more common adverse drug effects. But the rare and long latency adverse drug effects can be reported only when the medicine is consumed by a large population [1]. In a real-life setting, a larger and more diverse group of patients will take the medicines. They may have co-morbidities and they may be taking other concomitant medicines also. Some less common or rare side effects may only occur once a medicine has been used for a long time or duration by many people. It is therefore vital that the safety of all medicines continues to be monitored while they are in commercial use. Information is continuously collected after the medicine is placed on the market to monitor real-life experiences with the product. The Commission on Human Medicines (CHM) and Medicines and Healthcare products Regulatory Agency (MHRA) encourage the reporting of all suspected reactions to newly introduced medicines to the market.

Black Triangle Drugs (▼)

To ensure appropriate post-surveillance action regulatory authorities of the European Union (EU) was described some drugs as Black Triangle Drugs under the additional monitoring schemes in 2015. These are the drugs that are newly come to market or the existing drugs that are being used for a new reason and/or new route of administration, new drug delivery system and an established medicine which is to be used in a new patient population.

An inverted black triangle symbol (▼) is assigned to these drugs in Patient Information Leaflet (PIL), British National Formulary (BNF), Nurse Prescriber's Formulary (NPF), monthly index of medical specialities (MIMS), the electronic medicines compendium, advertising material, in product summary characteristics to indicate that there is relatively limited information about their safety from clinical trials. Additionally, the product which has been approved for significantly new indication or for use in a new population may have the Black Triangle symbol reinstated (▼*). Usually, an inverted black triangle symbol is maintained minimum for two years or till the well establishment of the drug safety [2].

The European Medicines Agency (EMA) maintains a list of all medicines that are under additional monitoring in the EU. These Black Triangle Drugs are new active substances, new medicines or vaccines, biological medicines or drugs derived from the plasma which require close monitoring by regulatory authorities to ensure that there should not be any serious adverse effects and/or complica-

tions. Regardless of the severity of adverse drug reactions, all healthcare professionals must have concerned to report any suspected adverse drug reactions [3].

Yellow Card Scheme

To corroborate the acceptably safe medicines for patients and users, UK regulatory authority introduced the Yellow Card Scheme where one can report any suspected reactions of vaccines, blood factors and immunoglobulins, herbal medicines, homoeopathic remedies, and all medical devices available on the UK market, defective medicines (those that are not of an acceptable quality), fake or counterfeit medicines or medical devices, nicotine-containing electronic cigarettes and refill containers (e-liquids) [4]. Counterfeit medicines or devices require obligatory actions to minimize the risk and maximize the benefit. Between January 2017 and December 2018, an interrupted time series analysis was conducted to compare the quantity of ADE reports pre, and post-the-black triangle intervention in Australia. The study concluded that there was a higher proportion of high-quality reports for black triangle medicines versus 2017 medicine. The black triangle scheme was marginally successful in improving ADE reporting [5].

Underreporting of Adverse Drug Reactions by Patients and Healthcare Professionals

A study in the department of psychiatry revealed underreporting of ADRs by patients and healthcare professionals [6]. Accelerated drug approval compromises safety and efficacy at the larger population. Hence it is important to report any ADR. Educating the public in this regard is crucial. Selective reporting bias to the Committee on Safety of Medicines, with general practitioners, showed a greater proportion of adverse reactions that are of greatest clinical concern. The message that doctors should submit yellow cards for all suspected adverse drug reactions to "black triangle" drugs should be reinforced. Under-reporting is a part of GP's (General Practitioner's) day-to-day activities. The selection process indicates that spontaneous reporting in general practice is not conducive to an exhaustive description of the safety profile of a drug.

Role of doctors and pharmacists in understanding black triangle drugs

Doctors and pharmacists must have up-to-date on drugs that enter the market, their known adverse effects, modified dosage formulations of existing drugs, different routes of administration and risk, and benefit ratio of existing drugs. Pharmacists should provide enough safety information to other health care professionals and the general public regarding essential steps to be taken to report adverse drug reactions and ensure that the patients are counselled properly. Doctors should be highly vigilant once these black triangle drugs prescribed to their patients and educate patients to report any side effects irrespective of its nature and severity.

An observational study was conducted on 'underreporting of suspected adverse drug reaction to newly marketed ("black triangle") drugs in general practice' in England. The Drug Safety Research Unit (DSRU) conducted observational cohort studies (Prescription even monitoring) on selected newly marketed drugs (10 drugs) in general practice. There were 3045 adverse events (in 2034 patients) reported as suspected adverse drug reaction on green forms during the 10 studies [6].

Conclusion

Adverse drug reactions are one of the common drug related problems encountered while we are using drugs. Documenting and reporting ADRs enable us to know detailed safety profile of drugs. Adverse reactions are, however, still grossly underreported and the many countries drug regulatory bodies asks all doctors and other healthcare professionals to report all suspect adverse drug reactions with new drugs (which have an inverted black triangle in the British National Formulary, MIMS, and the datasheets), and serious reactions only with older established drugs.

Source of Funding

None.

Conflict of Interest

None.

Reference

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