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Review Article

Pharmacovigilance is Important for Assessments of Drugs, and Withdrawal of the Drugs that have Adverse Effects More than The Benefits of Their Treatment

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Abstract

Pharmacovigilance is concerned with the adverse effects of the authorized drugs after use, hence if the adverse effects are harmful and deteriorate other organs or tissues of the patient.

These adverse effects were reported by the patients, pharmacists, nurses, clinicians, and physicians. Some examples which withdrawal from the markets according to the pharmacovigilance: astemizole, cisapride, terfenadine, and rofecoxib, which revealed many adverse effects leading to their withdrawal these drugs from the markets.

Aim of the research: The knowledge around pharmacovigilance and improving the side effects of drugs which present in the market, the results of this improvement led us to obtain new drugs without serious side effects.

We conclude that the market drugs improved from the older drugs, have side effects will are suitable to the usage by patients.

Introduction

Pharmacovigilance is bound with the information obtained from the patients after taking the drugs and improvement of the side effects of drug usage to obtain drugs less than the previous ones.

We chose four drugs as examples of drugs that have serious side effects when used by patients, and attempts by scientists to improve these drugs and eliminate their side effects [1-14].

Pharmacovigilance depends on the detection, assessment, understanding, and prevention of adverse effects or any drug-related problems associated with the pharmaceutical products, i.e., these processes for ensuring the safety of medicines after authorized for use [15-29].

These involve monitoring their use in everyday clinical practice, assessing risks, benefits, and providing information to healthcare professionals and patients.

The drug approval processes are discovery, drug design and completely ensuring the accurate structure of the drug, hence the second stage is the preclinical which carry on animals and monitoring the effect of the drugs to ensure the purpose of treatment, after that the clinical researches on volunteers of patients, and applied the blind trials on patients on different areas, the last stage the approval of drugs from the global organizations e.g. FDA.

From the previous information, some adverse effects are not observed at the stages of new drugs, not merely, but if the

drug is taken with other drugs will be expected the drug drug interactions which are not taken in our mind in the stages of drug approval.

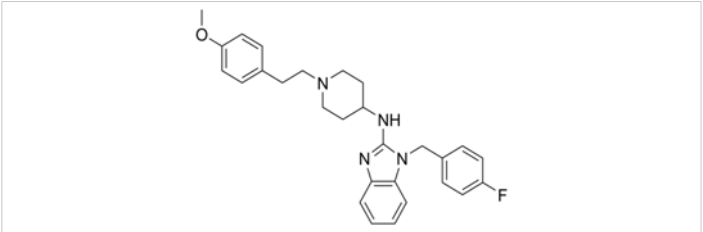
The pharmacovigilance plays an important role, specifically after authorizing the drug to assess the benefits and adverse effects, where the adverse effects may have fetal effects compared with the benefits of treatments, hence the drug must be withdrawn from the market and its uses.

The pharmacovigilance is a returned knowledge from the watches of patients, nurses, pharmacists, clinicians, and physicians; these watches are written as reports to the stakeholders, for example: prescribers, drug manufacturers, and the healthcare organizations.

Pharmacovigilance of some drugs

Some drugs which are used in the treatment of many diseases are withdrawn from the market according to the watchful monitoring of the adverse effects, which is desirable compared with the treatment benefits of these drugs, or are lethal in the long run, for example:

1. Astemizole: marketed under the brand name hismanal, was a second-generation antihistamine drug that had a long duration of action, more than the first generation of H_1-antagonists. Hismanal was used from 1977 till 1999 and withdrawn due to potentially fetal side effects (QTc interval prolongation and related arrhythmias)



Astemizole

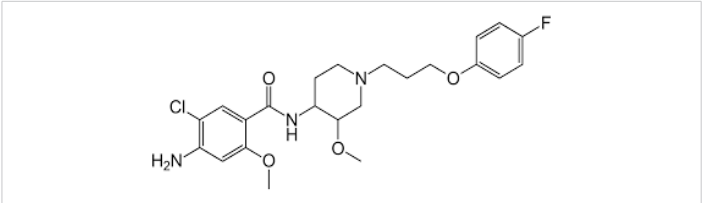
It was used as an antihistaminic and withdrawn from the market due to its side effects.

Astemizole has long duration of action, this effect is make the drugs more effective than H_1-antagonist, this property may be play role in its side effects after introducrd these drug to the market watched the adverse effects on the heart, hence when compare the adverse effects with the benefit of antihistaminic action the drug is low effective due to these reasons, so the drug withdrawn from the market this drawing according to the pharmacovigilance of the drug and reports from the physicians, pharmacists, nurses and patients.

Specifically, the price of the antihistamine, which is astemizole, is cheaper compared to the adverse effects that require treatment with expensive costs.

2. Cisapride: It is a gastroprokinetic agent, a drug that increases motility in the upper gastrointestinal tract, acts directly as a serotonin receptor agonist (5-HT_4), and acts directly as a parasympatho-mimetic, where stimulating the serotonin receptors leads to increased acetylcholine release in the enteric nervous system. Cisapride was introduced to the market under the brand name Prepulsid in 1980 and withdrawn from the market because of its serious cardiac side effects, which were linked to children's deaths.

The cisapride side effects are its potential to cause cardiac issues. The medications have been linked to serious cardiac arrhythmia, including torsades de pointes, a life-threatening form of ventricular tachycardia. This risk is heightened in individuals who have preexisting heart conditions, electrolyte imbalances, or who are taking other medications that can prolong the QT interval.

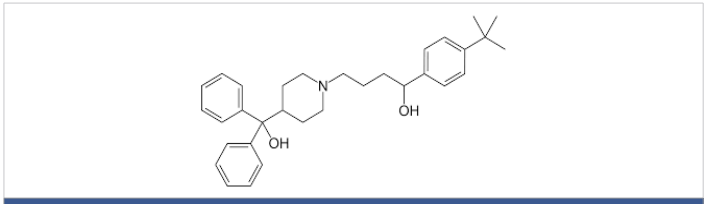


Cisapride

It was used in the treatment of gastroesophageal reflux disease and withdrawn from the market due to its side effects.

From the previous knowledge exist reports of pharmacovigilance. The drug was withdrawn from the market because of its serious side effects, which require more expensive costs to manage compared with the benefits of the treatment, as the drug acts on the GIT not merely, but the drug interaction with other drugs may cause these serious side effects of cisapride. The pharmacovigilance plays an important role in preventing these serious side effects.

3. Terfenadine: It is an antihistaminic drug used to treat allergic manifestations. It was marketed by Hoechst Company (sanofi company) under the brand name Triludan. It was withdrawn from the market because of its dangerous risks of the particular type of disruption of the electrical rhythms of the heart, specifically cardiac arrhythmia caused by QT interval prolongation.



Terfenadine

It was used as an antihistaminic and withdrawn from the market due to its side effects.

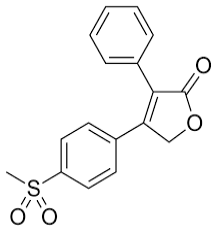
The terfenadine replaced by fexofenadine because its side effects on the heart, the fexofenadine is drug designed on to

improve the effects of terfenadine and to prevent the side effects of terfenadine on heart, N.B. the pharmacovigilance is used to as good idea for drug design where improve the side effects of drugs by prevent these side effects, also pharmacovigilance gave us the causes of improvement of drugs or withdraw the harming drugs which authorized and used in the market.

4. Rofecoxib: It is a Non-steroidal anti-inflammatory drug (NSAID) which is acts on COX2 selectively which used to treat osteoarthritis, rheumatoid arthritis, juvenile arthritis, acute pain conditions, migraine, and dysmenorrhea. This drug is marketed under the brand name Vioxx.

This drug was withdrawn in 2004 because of an increased risk of cardiovascular events, which is confirmed by new evidence.

Rofecoxib is linked with heart attacks and strokes in people who have cardiac bypass surgery.



Rofecoxib

It was used as an analgesic and anti-inflammatory, and withdrawn from the market due to its side effects.

The pharmacovigilance reports of rofecoxib tell us the serious adverse effects of its on the heart, hence the benefits of rofecoxib treatment compared with the serious side effects led its manufacturer to withdraw it from the market.

Conclusion

Pharmacovigilance plays a critical and ongoing role in safeguarding public health by ensuring the post-marketing safety of pharmaceutical products. While rigorous preclinical and clinical trials are conducted before drug approval, some adverse effects—especially those arising from long-term use, polypharmacy, or rare interactions—may only become evident during widespread clinical use. As demonstrated by the withdrawal of drugs such as astemizole, cisapride, terfenadine, and rofecoxib, pharmacovigilance systems are vital in detecting and evaluating these unforeseen risks.

Through systematic collection and analysis of reports from healthcare professionals and patients, pharmacovigilance enables regulatory authorities and pharmaceutical companies to assess the risk–benefit profile of drugs continuously. In cases where adverse effects outweigh therapeutic benefits, these insights guide decisions to restrict or withdraw the drug from the market, protecting patients from potentially fatal outcomes.

Moreover, pharmacovigilance contributes to the advancement of drug design and development by identifying harmful pharmacological mechanisms and informing the creation of safer therapeutic alternatives, as seen in the development of fexofenadine to replace terfenadine. Therefore, pharmacovigilance not only ensures drug safety but also drives innovation and improvement in pharmaceutical care.

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