A Study on recent development of Pharmacovigilance programme for Adverse Drug Reaction Monitoring of Antidepressant

Keerti Bhardwaj*, Arun Sharma, Sachin Kumar Singh, Iqbaljit Kaur

Department of Pharmaceutics, Lovely School of Pharmaceutical Sciences, Lovely Professional University, Phagwara, Punjab, 144411.

Abstract

Depression is a lifestyle disorder followed by unhealthy thoughts and excessive stress and anxiety and as much as it can cause the damage, it is very difficult to identify specially at earlier stages and its treatment do not just includes medications but therapy as well. The medications that have been approved from FDA are very selective as they affect the brain directly and thus their doses have to be monitored throughout the treatment. While these medications help the patient to cope with depression, some adverse events may also occur at the time of pharmacotherapy. Thus a strict vigilance has to be applied over the action of such drugs on the brain to avoid any undesired event. In this study the pharmacovigilance programme for antidepressant drugs has been observed and their adverse drug reactions were studied.

Introduction

The word “pharmacovigilance” is a mix of a Greek word pharmakon which means ‘drug’ and a Latin word vigilare which means ‘to keep watch’. It is the related to detection, collection, assessment, monitoring and prevention of adverse effects of drug formulations. Pharmacovigilance focuses on the adverse events and undesired actions caused by the pharmaceutical product such as insufficient pharmacological performance, contraindications, hypersensitivity, drug interactions or toxicity. When done properly, the pharmacovigilance identifies these risky scenarios in the shortest possible time and then attempt to minimize them is the next step towards improving the formulation. A key aspect of this study is to identify the benefit vs risk ratio and to decide whether the risk present is worth taking with respect to the benefit provided by the drug to the patient. For example, if a life-saving drug is causing hair loss then the benefit is way more than the adverse effect of hair fall and thus is risk is worth taking to save the patient’s life. However, the same side effect with a headache curing drug will outweigh the benefit and will not be acceptable.

Depression is a common but very serious mental illness which hits the person's daily life directly by altering their thoughts, with a feeling of worthlessness in every aspect of life and life as a whole and the person stops feeling the emotions of happiness, joy and excitement. However, depression can be treated.

Symptoms of depression may include:

- Sad and depressed mood
- Loss of interest and excitement in those activities which were liked by the person earlier
- A sudden increase or decrease in appetite
- Sudden change in sleeping patterns, either sleeps too much or not at all
- Lack of energy in body
- Feeling of worthlessness and guilt
- Difficulty in concentration, rational thinking and decision making
- Suicidal thoughts

Depression when left untreated may results into serious problems like substance abuse or addiction, increased chances of inappropriate behavior leading to damaged relationships, professional troubles and difficulty in treating other diseases. The clinical depression affects the mood, thoughts and body and may last for years if left untreated. Without treatment, it has the potential to force the person to live life miserably or encourage them to end their lives. The proper treatment with antidepressants and/or psychotherapy is required to manage and treat this illness.

Antidepressants, the drugs prescribed for the treatment of depression includes selective serotonin reuptake inhibitors, tricyclic antidepressants, monoamine oxidase inhibitors, tetracyclic antidepressants and others. These antidepressants are prescribed when no other therapy or treatment is effective as they have the potential to alter the brain activities. Therefore, when given to a patient, its actions must be closely monitored. It has been observed in cases when any new antidepressant has been used, suicide was considered as a possible side effect of the drug. Especially in adolescent children.

Adverse drug reaction (ADR)

According to WHO, a noxious and undesirable response of a drug at a normal dose for diagnosis, prophylaxis or treatment therapy of any illness or physiological function modification. It is the unpleasant and harmful reaction caused by the drug having higher risk ration than the benefit and requires to be changed in order to avoid the potential risk caused by the drug. Types of ADR are:

- Dose-related
- Allergic
- Idiosyncratic

Adverse drug event (ADE)

As per WHO, any untoward occurrence that generated during the treatment of any illness with the help of a pharmaceutical product but is not directly related to the treatment. Adverse drug events may occur due to any medication error or due to any ADRs.

Signal

It is an indicative information related to any adverse drug event of a drug which hints towards the possibility of presence of any adverse drug reaction.

Aim of pharmacovigilance

- Increased quality of patient healthcare and safety in regards of use of drugs and other medical, paramedical devices.
- Contribution in assessment of harm, benefits, risks and effectiveness of medicines, enhancement of rational, safe and cost effective use of drugs.
- Spreading awareness, knowledge and laboratory training for pharmacovigilance and its proper communication with the healthcare providers and professional as well as public.

Pharmacovigilant study on antidepressants

Sr.No.	**Name of Antidepressant**	**Doses mg/day**	**Therapeutic index (TI)**	**Adverse drug reaction**	**Overdose toxicity**
1	Amitryptyline	100	Small	Numbness and tingling in arms and legs, confusion, headache, skin rash, constipation or diarrhea, unexpected weight gain or loss, swelling on face and tongue, blurred vision, nausea	High

2	Amoxapine	50-100 max dose: 600	Small	Light headache, confusion, constipation, dizziness, dry mouth , difficulty in urination	-
3	Clomipramine	25 ,100, 250	Small	Light headache, confusion, constipation, dizziness, dry mouth , difficulty in urination	Moderate
4	Desipramine	100-300	Small	Light headache, confusion, constipation, dizziness, dry mouth , difficulty in urination	-
5	Doxepin	25-300	Small	Light headache, confusion, constipation, dizziness, dry mouth , difficulty in urination	-
6	Imipramine Hydrochloride	10-50	Small	Light headache, confusion, constipation, dizziness, dry mouth , difficulty in urination	High
7	Imipramine Pamoate	10-50	Small	Light headache, confusion, constipation, dizziness, dry mouth , difficulty in urination	High

Conclusion

Depression when left untreated may results into serious problems. The medications for that are very selective as they affect the brain directly and thus their doses have to be monitored throughout the treatment. While these medications help the patient to cope with depression, some adverse events may also occur at the time of pharmacotherapy. Thus a strict vigilance has to be applied over the action of such drugs on the brain to avoid any undesired event.

References

1. Biswas P, Biswas A. Setting standards for proactive pharmacovigilance in India: The way forward. Ind J Pharmacol 2007;39:124-8.
2. Skalli S, Soulaymani Bencheikh R. Safety monitoring of herb-drug interactions: a component of pharmacovigilance. Drug Saf 2012;35:785-91.
3. Arnott J, Hesselgreaves H, Nunn AJ, Peak M, Pirmohamed M, Smyth RL, et al. What can we learn from parents about enhancing participation in pharmacovigilance?. Br J Clin Pharmacol 2012; in press.
4. Gerritsen R, Faddegon H, Dijkers F, van Grootheest K, van Puijenbroek E. Effectiveness of pharmacovigilance training of generalpractitioners: a retrospective cohort study in the Netherlands comparing two methods. Drug Saf 2011;34:755-62.
5. Kshirsagar N, Ferner R, Figueroa BA, Ghalib H, Lazdin J. Pharmacovigilance methods in public health programmes: the example of miltefosine and visceral leishmaniasis. Trans R Soc Trop Med Hyg 2011;105:61-7.
6. The importance of pharmacovigilance. Geneva: World Health Organization; 2002.
7. Joshi SR, Sapatnekar SM. Pharmacovigilance in India: how safe are the new drugs? How sure are we? J Assoc Physicians Ind 2008;56:933-4.
8. Olsson S. Pharmacovigilance training with focus on India. Ind J Pharmacol 2008;40: S28-S30.
9. WHO, Pharmacovigilance: ensuring the safe use of medicines, Geneva: WHO 2004.
10. The Importance of Pharmacovigilance, WHO 2002.
11. WHO Medicines Strategy: Framework for Action in Essential Drugs and Medicines Policy 2000-2003.