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Levosulpiride – Sixteen Years Experience at Tertiary Care Centre of Northern India.

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Abstract: ***Introduction***: Levosulpiride is a substituted benzamide that acts as a selective dopamine (D2) receptor antagonist and prokinetic agent. It is prescribed for psychiatric conditions (schizophrenia, depression) and gastrointestinal disorders (GERD, functional dyspepsia, irritable bowel syndrome). It is usually prescribed for short durations (4 to 8 weeks) to treat stomach-related ailments and most common side effects are somnolence, fatigue, weight gain, galactorrhoea, and hyperprolactinemia. It is contraindicated during pregnancy, lactation, and in children under 15 years of age. ***Case report:*** **–** Our Medical Gastroenterology department is tertiary care center in Northeren India and is a high flow center and caters different kind of gastro-intestinal patients from different surrounding states. We have sixteen years of experience of using levosulpiride and thousands of patients have been treated with this drug. We are running twice weekly gastroenterology clinic in which on an average 250-300 patients come for consultation. In rest four days of week, we run hepatitis clinic in which also many patients have associated gastritis problem. On an average, every month 300-400 patients are prescribed oral levosulpiride in daily dose of 75 mg. Moreover, we have 20 bedded indoor wards where many patients need injectable levosulpiride (25 mg tid dosage). On an average, 100 patients/month are treated with injectable levosulpiride. Hence, in last 16 years we have treated thousands of patients with both oral and injectable levosulpiride. In the beginning, when we started using oral levosulpiride in young women, then around 20 % of them developed galactorrhoea due to hyperprolactinemia. In some cases, endocrinologist consultation for above complaints, led to unwarranted MRI brain for ruling out pituitary tumours. In some cases, even menstrual irregularities occurred. Hence, we stopped prescribing levosulpiride to young females and only in refractory cases we use for only one month. By this approach, we avoided the above side effects. Our second experience of using oral levosulpiride in elderly and young children of around 14 years showed no side effects, including extrapyramidal symptoms. But when levosulpiride was used in injectable form, then few patients (4 children and 5 elderly) developed EPS in form of abnormal movements and stiffness of limb, along with neck stiffness in some. Hence, we have stopped using both oral and injectable levosulpiride, as a precautionary measure in these groups. Thus, on basis of sixteen years long experience of using levosulpiride in thousands of patients, we can recommend that it is a good drug but has to be used cautiously for avoiding side effects which occur more frequently in young females, children and elderly. ***Conclusion:*** Every drug has well documented common side effects but treating doctor should be aware of rare and atypical side effects of every drug being prescribed by him or her. Levosulpiride is a good drug having pro-kinetic effect on both upper and lower gastro-intestinal tract. It has additional antipsychotic and anti-anxiety effects. It has well documented side effects of hyperprolactinemia and galactorrhoea in young females and extra-pyramidal side effects abnormal movements, stiffness of neck and limbs, especially with injectable treatment in elderly and children. Hence, we should avoid using levosulpiride in above groups.

Keywords: Levosulpiride, Dysarthria, Side effects, Dystonia, Tardive Kinesia.

INTRODUCTION

Levosulpiride, as a gastroprokinetic agent, has shown promising results in the treatment of various gastric disorders such as functional dyspepsia and non-erosive reflux disorder. [1] Chemically, it is a synthetic benzamide derivative with a strong inhibitory effect on dopaminergic D2 receptors both in the central nervous system and in the GIT. Studies have shown Levosulpiride to be effective in the treatment of various diseases such as dyspepsia (functional or organic), diabetic gastroparesis, reflux esophagitis, iatrogenic emesis induced by drugs such as chemotherapy, calcitonin, and anaesthetics, as well as non-iatrogenic nausea and vomiting. [2] It also acts as a moderate agonist at the serotonergic 5-HT4 receptor and to a lesser extent on 5-HT3 receptors.

[3,4] The serotonergic (5-HT4) component of Levosulpiride may enhance its therapeutic efficacy in gastrointestinal disorders.22 This property, together with antagonism at D2 receptors, may contribute to its gastrointestinal prokinetic effect. [5] Levosulpiride, a widely used prokinetic and antipsychotic medication, is frequently associated with Extrapyramidal Symptoms (EPS) and hyperprolactinemia.

Case reports document severe neurological and hormonal side effects—such as drug-induced Parkinsonism, akathisia, and neuroleptic malignant syndrome (NMS)—that often require immediate drug withdrawal and targeted medical intervention. Drug-induced Parkinsonism & movement disorders manifest as resting tremors, limb stiffness, rigidity, and acute dystonia within 9 to 164 days of starting the drug.

In some instances, these motor symptoms can be persistent or irreversible, requiring therapy with dopaminergic agents like pramipexole or levodopa. Hyperprolactinemia and galactorrhoea are caused by levosulpiride by dopamine D2 receptor antagonism, leading to blocking of inhibitory effect of dopamine on prolactin release. Case reports document patients (particularly females) developing hyperprolactinemia and spontaneous milky breast discharge (galactorrhoea). Restless Leg Syndrome (RLS) can also be triggered by levosulpiride which is characterized by an irresistible urge to move the legs, typically presenting in the evening. Neuroleptic malignant syndrome (NMS), though extremely rare, is life-threatening reaction marked by high fever, severe muscle rigidity, altered mental status, and rhabdomyolysis.

CASE SERIES

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DISCUSSION

Dopamine is a neurotransmitter known to be involved in the regulation of mood and behavior. Psychotic illness is thought to be caused due to disturbance of neurotransmitters (chiefly dopamine) in the brain. Schizophrenia is a psychotic illness characterized by

dopamine over activity in the brain and so anti dopaminergic drugs are a useful for the management of this disease. Levosulpiride is the levo enantiomer of sulpiride. It is a substituted benzamide which is meant to be used for several indications: depression, psychosis, somatoform disorders, emesis and dyspepsia, burning mouth syndrome, acute unilateral labyrinthine dysfunction, premature ejaculation and cataplexy. It is physically present as a white crystalline powder. [6] The well-known side effects are acute muscular dystonia, sedation or drowsiness, increase in plasma prolactin levels (manifested by breast enlargement, production of milk and stopping of menstrual periods), neuroleptic malignant syndrome, akathisia, tardive dyskinesia, postural hypotension, weight gain and elevated liver transaminases.[6]

Levosulpiride should either be used cautiously or is contraindicated in elderly people, children less than 14 years of age, Parkinson disease, severe renal or hepatic insufficiency, history of epilepsy, Porphyria's, breast cancer, alcohol intoxication, certain tumours like phaeochromocytoma & pituitary prolactinoma and hypokalaemia. The drug should be used cautiously in pregnancy (only when it is expected to benefit the mother more than the possibility of risking the fetus). The drug is known to be secreted in breast milk, so, its use should be restricted in breastfeeding women. Our long experience with levosulpiride is in alignment with above recommendations and we also suggest that it should not be used in children below 14 years, young females and elderly.

CONFLICT OF INTEREST- The authors declare there was no conflict of interest and no funding were taken for this case series.

CONCLUSION

Every drug has well documented common side effects but treating doctor should be aware of rare and atypical side effects of every drug being prescribed byhim or her. Levosulpiride is a good drug having pro-kinetic effect on both upper and lower gastro-intestinal tract. It has additional antipsychotic and anti-anxiety effects. It has well documented side effects of hyperprolactinemia and galactorrhoea in young females and extra-pyramidal side effects abnormal movements, stiffness of neck and limbs, especially with injectable treatment in elderly and children. Hence, we should avoid using levosulpiride in above groups.

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