Atypical Parkinson’s Takes Heaviest Toll on Patients

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San Diego — Atypical Parkinson’s disease took the most pronounced toll on patients’ ability to carry out essential daily activities among those among patients with Parkinson’s disease, reported Lisa M. Schulman, M.D., codirector of the Parkinson’s Disease and Movement Disorders Center at the University of Maryland in Baltimore, who reported her results in posterior format at the annual meeting of the American Neurological Association.

Significant variation was found in disability scores among patients with essential tremor (n = 58), dystonia (n = 50), Parkinson’s disease (n = 425), psychogenic movement disorders (n = 67), Alzheimer’s disease (n = 17), and atypical Parkinsonism (n = 45). All of the disorders significantly under-estimated physical quality of life, as measured by the SF-12v2 Health Survey, but atypical Parkinson’s disease patients had the lowest scores by far, reported Dr. Schulman and associates from the university’s department of neurology.

Just three of the disorders—Alzheimer’s disease, psychogenic movement disorders, and atypical Parkinsonism—showed reduced health-related quality of life scores measured by the SF-12v2 survey. Disability was assessed using the Older Americans Resources and Services scale, which includes activities of daily living (ADL) and instrumental activities of daily living (IADL) at a person’s best and worst level of function. Atypical Parkinson’s disease and Alzheimer’s disease had the greatest impact on all instrumental activities of daily living.

In general, neurodegenerative disorders (Parkinson’s disease and atypical Parkinsonism) and Alzheimer’s disease resulted in greater disability than essential tremor as well as other autonomic disorders.

Lyrica® (Pregabalin Capsules)

Lyrica is contraindicated in patients with known hypersensitivity to pregabalin or any of its components.

Warnings

Serious Impairment of Cardiac Function

Death, cardiac arrest, and serious cardiovascular events including QT prolongation and QTc prolongation have occurred in patients treated with pregabalin.

Pregnancy: Pregnancy Category C

Breastfeeding

Lyrica is excreted in breast milk and is contra-indicated in breastfeeding women.

Common Adverse Reactions

Appetite increase, weight gain, dizziness, somnolence, blurred vision, peripheral edema, constipation, somnorrhagia, alacrimia, constipation, anorexia, headache, rash, and cough.

CNS Overdose

Pregabalin is a sedative and can cause drowsiness, confusion, fatigue, and disorientation. The risk of CNS depression increases with the dose of pregabalin administered and with the presence of other CNS depressant medications.

Mutagenesis

Increased incidences of fetal structural abnormalities and increased incidences of postimplantation losses were observed in gestation studies in two species (rat and rabbit) following maternal administration of pregabalin (50 to 2500 mg/kg) throughout the period of organogenesis. Increased incidences of specific skull alterations attributed to abnormal ossification (fusion of the skull) and skeletal malformations were observed at doses of 100 mg/kg or greater in fetal rabbits at a level that exceeded the maximum recommended doses for humans.

Increased incidences of skeletal malformations were observed in rabbit fetuses following maternal administration of pregabalin (50 to 2500 mg/kg) prior to and during mating with untreated females. A number of skeletal alterations developed at doses of 300 mg/kg or greater. These included shortened carpal bones and forelimb anomalies such as phalangeal fractures, fractures of the metacarpus and radii, and a decrease in ossification of the metacarpus and radius.

Pregnancy: Pregnancy Category C

Increased incidences of skeletal malformations were observed in rat fetuses following maternal administration of pregabalin (50 to 2500 mg/kg) throughout the period of organogenesis. Incidences of specific skull alterations attributed to abnormal ossification (fusion of the skull) and skeletal abnormalities were observed at doses of 250 mg/kg or greater. In the absence of findings of adverse effects in rat fetuses following administration of pregabalin (250 mg/kg), exposure of rat preimplantation embryos was determined in a study in which pregnant rats were dosed with 250, 1250, or 7700 mg/kg. Pregabalin-related maternal toxicity, including bradycardia, incomplete placenta separation, and death, was observed in the 7700 mg/kg group. The effect on offspring survival was pronounced at doses of 1250 mg/kg and above.

The fates of the male and female offspring were assessed at 2, 4, and 16 weeks postnatal. There were no apparent effects on offspring survival. Postnatal assessment of male offspring included a testicular examination and an assessment of weight at 4 weeks postnatal. The results of these assessments were negative. Assessment of female offspring included a vaginal examination and an assessment of weight at 4 weeks postnatal. The results of these assessments were negative.

Disability was assessed using the Older Americans Resources and Services scale, which includes activities of daily living (ADL) and instrumental activities of daily living (IADL) at a person’s best and worst level of function. Atypical Parkinson’s disease and Alzheimer’s disease resulted in greater disability than essential tremor as well as other autonomic disorders.

ADVERSE REACTIONS

The most commonly reported adverse reactions across various patient populations during the premarketing development of pregabalin were: somnolence, headache, dizziness, nausea, and constipation. In patients with postherpetic neuralgia, 23% of patients treated with pregabalin reported dizziness, compared to 11% of patients treated with placebo. In atypical Parkinson’s disease patients, 45% of pregabalin-treated patients reported dizziness, compared to 3% of patients treated with placebo. In patients with Alzheimer’s disease, 36% of pregabalin-treated patients reported dizziness, compared to 4% of patients treated with placebo.

In a postmarketing surveillance database of >12,000 patients treated with pregabalin, the incidence of dizziness was 12.1% for all treated patients. The incidence of dizziness was highest in patients with postherpetic neuralgia, where the incidence was 21.7%. The incidence of dizziness was 11.9%, 10.7%, and 7.2% in patients treated with 150, 300, and 600 mg daily respectively.

No deaths were reported in patients treated with pregabalin, including in postmarketing surveillance databases of >12,000 patients treated with pregabalin. In general, although adverse drug reactions occurred in the placebo group, they were generally more frequent in the pregabalin group.