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Short Communication
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Relyvrio – For the Treatment of Amyotrophic Lateral Sclerosis

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Short Communication

Amyotrophic Lateral Sclerosis (ALS) also known as Lou Gehrig's disease, is a disease that results from progressive deterioration of motor neurons of brain and spinal cord which results in muscle weakness to the point of paralysis. It affects 6 per 100,000 with the highest prevalence in males, whites, and people with 60 years of age or older, with age increasing both, its prevalence and incidence. Potential risk factors for ALS include family history, heavy manual labored occupations, football, agricultural work, pesticides, chemicals, smoking and electric shocks [1].

The primary symptoms include unilateral but progressive weakness in the distal limbs without remission and relapse. Atypical presentation can include weight loss, cognitive impairment, emotional alteration and fasciculations. Muscle cramps and twitches with positive Babinski sign is also seen [1]. The duration between the onset of symptoms and diagnosis of ALS is about a year. And by that time nearly 50% to 70% of motor neurons become nonfunctional [1]. The Cleveland group, based on experimental design hypothesizes that the onset of disease is due to the vulnerability of motor neuron itself, whereas disease progression is the result of immune responses characterized by neuroinflammation, particularly the activation of microglia [2,3].

In the early 1990s, riluzole (rilutek), a putative blocker of glutamate release, was established as the first drug for ALS. Riluzole became the gold standard drug which paved the way for newly formulated drugs in the treatment of amyotrophic lateral sclerosis. There are currently five drugs for the management of ALS, namely Rilutek, Tiglutik, Exservan, Radicava and Nuedexta [4]. The first three being different formulations of generic Riluzole. Furthermore, Neudexta is indicated for the treatment of certain unspecific neurologic symptoms, but not for ALS itself.

FDA has approved a new oral drug named "Relyvrio" for the treatment of ALS in adults [5]. Experts had concerns regarding the effectiveness of the drug which were ruled out in updated clinical trials data. Relyvrio is a compound of two drugs, sodium phenylbutyrate and taurursodiol. Sodium phenylbutyrate helps in elimination of ammonia from the body while taurursodiol helps liver in detoxification [5].

The drug formerly known as AMX0035 can be taken orally or be administered through a feeding tube [5]. Relyvrio is taken within 1 h of its preparation either orally or through feeding tube. Initial dosing is one packet per day for starting three weeks (3 weeks) followed by a maintenance dose of one packet twice daily.

The efficacy of Relyvrio was tested in a 24-week multicenter, randomized, double-blind, placebo-controlled, parallel group study. The trial showed that the patients treated with relyvrio had a slower decline in daily functioning with longer overall survival as observed, as compared to controls on placebo [6].

The pathophysiological mechanism of action is aimed to reduce endoplasmic reticulum stress and mitochondrial dysfunction associated with protein misfolding and aggregation, the ultimate pathogenesis of ALS. Some potential side effects seen with the administration of relyvrio were diarrhea, abdominal pain, nausea, and upper respiratory tract infection. Taurursodiol, a bile acid, can affect patients with problems associated with enterohepatic circulation of bile acids, thus patients with liver dysfunction or with other known comorbid should consult a specialist before

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intake. The prescribing information lists additional risks associated with relyvrio's administration [6]. It's not known whether it's contraindicated in pregnant ladies or children.

ALS is a debilitating disease with a difficult diagnosis, poor prognosis, shorter survival periods and currently has no cure [1]. With the advances being made in drug therapies, relyvrio can be a breakthrough in the treatment of amyotrophic lateral sclerosis, with its enhancing effects on life expectancy, as compared to the old drugs in use for ALS. More studies investigating the efficacy and efficiency of Relyvrio in patients with ALS and other related neurological disorders and comorbidities are required to give a better insight of the long-term outcomes of the usage of drug for which longer and larger trials are required.

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