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Commissural Connections

Glatiramer Acetate three times per week

Samuel Pleasure, MD, Neurology, 02:52PM Aug 20, 2013

As those of us who treat MS patients know, Copaxone (glatiramer acetate - GA) is one of the more easily tolerated first line therapies for MS. One of the chief problems is the need for daily subcutaneous injections, which are both wearisome and associated with injection site reactions. Many patients express frustration with this over time. The typical dose is 20mg per day but previous studies showed that 40mg per day was safe, although didn't confer major advantages. A recent study published in Annals of Neurology (Khan et al., June 2013) shows that 40mg injections 3x week are an effective therapy for RRMS. Clearly, the makers of GA are positioning themselves to try to keep a portion of the market that they see as imperiled with the advent of dimethyl fumarate (Tecfidera).

The study is only modestly interesting and really not terribly surprising but the reason why I am mentioning it here is that on reading it I was reminded of one of the real shortfalls in the way these studies are done. By way of disclosure, I am a neurologist who treats MS patients and a basic researcher, I am not significantly involved in clinical trials at this time.

What alarmed me about this study is that 3x weekly GA was compared to placebo in patients with RRMS who have been having at least 1-2 attacks in the previous 1-2 years. It seems fairly unethical to me to compare 3x weekly GA to placebo, when clearly the intention of the authors is to ask if 3x weekly is comparabe to daily 20mg dosing. There could easily have been a design to compare 3x weekly to daily (using dummy injections, as were done for the placebo) to maintain blinding. I find it difficult to understand why it is sensible to have an inactive arm for patients who clearly need treatment. I personally think that the design of MS trials should be overhauled a bit to compare putative active drugs to proven active drugs and in particular in this case where the question is just one of dosing, it seems a bit disingenous to compare to placebo. The real question is whether it is similarly active to daily GA.

Am quite curious whether others feel the same.

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ABOUT THIS BLOG

Commissural Connections will discuss issues of interest to neurologists, focusing on basic science with significant translational implications for neurologists.

Disclosure: Samuel J. Pleasure, MD, PhD, has disclosed no relevant financial relationships.



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Samuel Pleasure, MD, PhD, is Professor of Neurology at UCSF. He got his MD and PhD (Neuroscience) degrees at the University of Pennsylvania and then trained in neurology and neuroscience at UCSF. He has authored numerous scientific papers on the basic mechanisms of brain development and how they relate to human neurodevelopmental disorders. He has clinical interests in epilepsy and multiple sclerosis.

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