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Randomized, Prospective, Rater-Blinded, Four Year Pilot Study To Compare the Effect of Daily Versus Every Other Day Glatiramer Acetate 20 mg Subcutaneous Injections in RRMS

Christina Caon, Detroit, MI, Alexandros Tselis, Rochester Hills, MI, Wendy Ching, Moeein Din, Imad Zak, Zahid Latif, Fen Bao, Samia Ragheb, Alan Hudson, Omar Khan, Detroit, MI

OBJECTIVE: We conducted a pilot trial to compare the effect of GA 20 mg SC daily to every other day (QOD) on clinical, MRI, and immunologic outcomes in RRMS. **BACKGROUND:** The recommended dose of glatiramer acetate (GA) for the treatment of RRMS is 20 mg SC daily though the optimal dose remains unknown. Recent studies failed to show improved efficacy with higher than the recommended dose. **DESIGN/METHODS:** Treatment naïve RRMS patients were randomized to GA 20 mg SC QD or QOD and followed prospectively for 2 years. After 2 years, patients in each group were given the option to continue or switch to the other group, and followed for an additional 2 years. EDSS was recorded every 6 months by a masked-rater. Brain MRI scans were obtained at baseline, years 2 and 4. Blood for immunologic testing was obtained at baseline and multiple time points after randomization. **RESULTS:** 30 patients were randomized to GA 20 mg SC given QD or QOD. Both groups were matched for age, disease duration, EDSS, relapse rate, and T2W lesions. After 2 years, there were no difference in the relapse rate, disease progression, or any MRI outcome. In vitro GA-proliferative responses and Th1/Th2 cytokine expression did not differ between the two groups at any time point after randomization. After 2 years, all patients in the QD group opted to switch to QOD. After a total of 4 years of prospective follow-up, there was no difference in the clinical efficacy between the "QD-QOD cross over" and the "always QOD" groups. Injection related lipoatrophy was significantly less in the QOD group. **CONCLUSIONS/RELEVANCE:** This pilot study suggests that GA 20 mg SC administered QD or QOD may be equally effective in RRMS. Larger, multi-center studies are warranted to confirm our findings and identifying the optimal dose of GA in RRMS.

Supported by: Wayne State University Neuroscience Program.

Disclosure: Ms. Caon has nothing to disclose. Dr. Tselis has nothing to disclose. Dr. Ching has nothing to disclose. Dr. Din has nothing to disclose. Dr. Zak has nothing to disclose. Dr. Latif has nothing to disclose. Dr. Bao has nothing to disclose. Dr. Ragheb has received research support from Teva Neuroscience. Dr. Hudson has nothing to disclose. Dr. Khan has received personal compensation for activities with Teva Neuroscience, Serono, Biogen Idec, and Bayer Health Care. Dr. Khan has received research support from Teva Neuroscience, Serono, Biogen Idec, and Bayer Health Care.

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