Onabotulinum Toxin-A Injections for Nocturnal Bruxism: A Parallel, Double Blind, Placebo Controlled Polysomnographic Study (P05.006)

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Objective: To test the safety and efficacy of onabotulinum toxin-A injections into the masseter/temporalis muscles in patients with nocturnal bruxism.

Background Bruxism is probably the most common parasomnia, occurring in up to 15% of the population. There is no widely accepted treatment other than bite guards to limit dental damage.

Design/Methods: We performed a double blind, placebo injection controlled (1:1) trial of onabotulinum-A (BoNT) for nocturnal bruxism. Patients underwent a baseline/screening overnight polysomnogram (PSG). They were then randomized to receive BoNT or placebo into the bilateral masseter (60u/side) and temporalis muscles (40u/side) using visual landmarks. Primary efficacy points were CGI and VAS of change at 4 weeks post injection. Secondary points including change in PSG data, including masseter placed electrodes, pain scales, sleep scales, adverse events, and need for follow-up open label injection.

Results: Eight subjects were excluding after the initial PSG prior to randomization (six for lack of bruxism on PSG and two declined to continue). Twenty-three (19 female, age 47.4(16.9) were randomized. Almost all reported temporal-mandibular pain. All 13 randomized to drug and 9/10 randomized to placebo completed the study. CGI ($p<0.05$) and VAS of change ($p<0.05$) favored the BoNT group. Secondary scales including the Headache Impact Test-6, total Pittsburgh Sleep Quality Index, Epworth Sleepiness Scale, and Self-Rated Anxiety Scale were not significantly changed. A large percentage of subjects had moderate obstructive sleep apnea on PSG despite lack of typical risk factors. The mean duration to open label f/u injection was 107 days in those randomized drug vs. 40 days in those randomized to placebo. .Adverse events were limited to 2 subjects with a cosmetic change in their smile. No dysphagia was reported.

Conclusions: BoNT effectively and safely improved nocturnal bruxism in this small pilot trial. Multi-center confirmatory trials are justified.