PW01-224 - **NEUROPSYCHIATRIC SYMPTOMS IN SMOKERS QUITTING WITH VARENICLINE OR PLACEBO: A DOUBLE-BLIND, RANDOMIZED, CONTROLLED PILOT STUDY**

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Objective: Varenicline is an α4β2 partial nicotinic agonist approved for smoking cessation. There have been spontaneous postmarketing reports of neuropsychiatric adverse events (NPAEs) in smokers without a history of psychiatric illness quitting with varenicline.

Methods: 110 smokers without history of psychiatric illness (screened by Structured Clinical Interview for DSM) were randomized to 12 weeks of varenicline (n=55) (1mg bid) or placebo. Adverse events were solicited systematically. Depressive symptoms, anxiety symptoms, aggression and irritability were measured at baseline and weekly using the Montgomery-Asberg Depression-rating scale (MADRS), the Hamilton Anxiety scale (HAM-A), and the Overt Aggression scale-modified (OAS-m). The Profile of Mood States (POMS) was administered daily. Mixed Model analysis of repeated measures was conducted to compare mean changes in scores between groups across the study period.

Results: Smokers had a mean age of 33; smoked on average 22 cigarettes/day with mean Fagerstrom score for Nicotine Dependence >7 at baseline. Reported NPAEs were similar between groups. No suicidal events were reported. There were no significant differences between groups for the MADRS (treatment difference vs. placebo [TD] = 0.03, 95% CI: -0.68, 0.73; NS), HAM-A (TD = 0.14, 95% CI: -0.62, 0.90; NS), OAS-m irritability subscale (TD = 0.08, 95% CI: -0.17, 0.34; NS), OAS-m aggression subscale (TD = 0.5, 95% CI: -1.18, 2.18, NS) and the POMS total scores (TD = 0.5, 95% CI: -0.52, 1.53; NS).

Conclusions: There were no significant differences between groups on measures of depressive symptoms, anxiety and aggression/hostility. Systematically solicited NPAEs were similar between varenicline and placebo.

https://doi.org/10.1016/S0924-9338(10)71631-X Published online by Cambridge University Press