DEXTROMETHORPHAN/QUINIDINE FOR PSEUDOBULBAR AFFECT: EFFICACY EVALUATION IN PATIENTS USING CONCOMITANT SSRIS

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Objective/Background: Dextromethorphan/quinidine (DM/Q) is under FDA evaluation to treat pseudobulbar affect (PBA) secondary to neurologic disease or injury. SSRIs have served as off-label treatment for PBA, but supportive data are limited to small trials and case reports. A Phase III, double-blind, placebo-controlled trial of two doses of DM/Q, in patients with PBA secondary to amyotrophic lateral sclerosis or multiple sclerosis, included patients taking concomitant SSRIs. This analysis assesses whether SSRI coadministration affected DM/Q therapeutic response.
Design/Methods: Patients received DM30mg/Q10mg (DM/Q-30), DM20mg/Q10mg (DM/Q-20) or placebo BID for 12 weeks. SSRI users on stable dosage for at least 3 months prior to randomization were permitted to constitute up to 10% of anticipated enrollment. A Center for Neurologic Studies¨CLability Scale (CNS-LS) baseline score of ¡□13 was required for enrollment. Patients with clinical depression and Beck Depression Inventory score >19 were excluded.
Results: Of 326 patients, 26 (8.0%) were taking SSRIs. Mean baseline CNS-LS scores were comparable for SSRI and non-SSRI users (20.8 and 20.2, respectively). Among 300 observed cases at Day 84, mean CNS-LS change was ¨C8.2 for DM/Q-30, and ¨C8.2 for DM/Q-20, vs ¨C5.7 for placebo (P=0.0002 and P=0.0113). For the 23 SSRI users vs 277 nonusers, mean CNS-LS change was ¨C7.7 vs ¨C7.3 (P=0.8415). By random-effects analysis, SSRI usage did not influence change in PBA episode rate (P=0.1671).
Conclusions: SSRI coadministration did not impact DM/Q therapeutic benefit for the treatment of PBA.
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