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Ropinirole In The Treatment Of Motor Deficits After Stroke: A Randomized, Placebo-Controlled, Double-Blind Study.

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INTRODUCTION: Several studies suggest the potential to improve motor status in patients with stroke by modifying the function of brain catecholamine receptors. Dopamine receptors are an attractive target given the importance of this neurotransmitter to a multitude of processes including attention, learning, motivation, and motor function. The current study hypothesized that a 9-week course of the dopamine agonist Ropinirole plus physical therapy (PT) would be a safe and effective way to increase gait velocity. METHODS: Entry criteria included stroke 1–12 mo prior, no depression (HAM-D score < 17), moderate motor deficits (arm/leg Fugl-Meyer score 23–83/100), and 50 foot walk > 15 sec. Patients were randomized (double-blinded, stratified for time post-stroke) to 9 weeks of Ropinirole (ROP) or placebo (PLAC), with doses (0.25mg - 4mg QD) titrated weekly as tolerated. All subjects received 8 PT sessions focused on gait, leg, and arm, in weeks 5–9. Assessments extended to week 12, i.e., 3 weeks after drug washout. The primary endpoint, gait velocity, was analyzed using repeated measures ANOVA to examine differences in treatment groups over the 9 weeks of therapy. RESULTS: At 3 U.S. sites, 744 patients were screened and 33 enrolled (age 61 +/- 14 yr; time post-stroke, 30 +/- 15 wks; mean +/- SD). Of these, 16 were randomized to PLAC+PT and 17 to ROP+PT (mean final daily ROP dose, 2.6 mg). Across all patients, significant gains were found over time for the primary endpoint, gait velocity at week 9 ($p=0.0001$), and for most secondary endpoints, with gains still significant at week 12. However, gains did not differ by treatment assignment (time X group interaction non-significant), for example: gait velocity increase from baseline to week 9 went from 0.54 +/- 0.37 to 0.72 +/- 0.46 (ROP+PT) vs. from 0.49 +/- 0.28 to 0.69 +/- 0.40 (PLAC+PT, $p=0.88$); and SIS-16, from 56 +/- 10 to 66 +/- 9 vs. from 58 +/- 11 to 65 +/- 9 ($p=0.72$). None of the 5 serious adverse events was attributable to drug effects. Outside therapy during the study was common, e.g., 61% patients received outside PT (mean 12 sessions). Of patients who received ROP, 93% accurately guessed treatment assignment. Results of serial functional MRI testing will be presented. CONCLUSIONS: PT improves motor function in patients with chronic stroke. PT was also commonly prescribed as standard of care outside of study-related interventions. At the doses achieved in this trial, ROP was safe but did not show any improvement over and above the favorable effects of PT. CLINICALTRIALS.GOV IDENTIFIER: NCT00221390

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