**PDN1**

**PATIENT SELF-ASSESSMENTS IN ADVANCED PARKINSON’S DISEASE WITHIN UPDRS AND “OFF” TIME SUBGROUPS: COMPARISON OF IPX066 WITH IMMEDIATE-RELEASE CARBIDOPA-LEVDOPA

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OBJECTIVES: We performed a systematic review of randomized controlled trials (RCTs) to estimate the efficacy of melatonin versus placebo or other hypnotic agents on the improvement of sleep quality and quantity in patients with primary insomnia. METHODS: We searched the published literatures in eight electronic databases, including Ovid-Medline, EMBASE, the Cochrane Library, and five Korean databases through October 2014. We included articles comparing efficacy for sleep between melatonin/placebo or other dissociated hypnotic agents. RESULTS: The quality of studies was evaluated by using the Cochrane’s risk of bias. The mean difference (MD) or standardized mean difference (SMD) was calculated using a random-effects model. CONCLUSIONS: Melatonin showed to be effective for sleep in comparison with placebo, thus can be an effective option for the treatment of insomnia. Further studies are needed to conclude safety profiles, economic usefulness and tolerance of melatonin.

**PDN2**

**THE EFFICACY OF MELATONIN FOR PRIMARY INSOMNIA: A SYSTEMATIC REVIEW AND META-ANALYSIS**

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**OBJECTIVES:** The evidence base for off-label agents used for relapsing-remitting MS. Here we report the key efficacy, safety, and post hoc analyses from the randomized, placebo-controlled phase 3 trials TEMSO and TOWER (NCT003134563) and TOWER (NCT00751881). METHODS: In TEMSO/TOWER, a total of 1088/1169 patients with relapsing MS were randomized (1:1:1) to once-daily teriflunomide 14 mg, teriflunomide 7 mg, or placebo. Treatment duration was 108 weeks (TEMSO) or variable, based on time of enrollment (TOWER, 48–152 weeks, ending 48 weeks after last patient randomized). Primary and key secondary endpoints were annualized relapse rate (ARR) and disability progression defined by Expanded Disability Status Scale (EDSS) at 2, 4, 6, and 5 years. RESULTS: Severe relapses as measured by Panitch definition; (D) relapses leading to hospitalization; and (D) relapses requiring intravenous corticosteroids. RESULTS: Teriflunomide 14 mg significantly reduced both ARR and disability progression vs placebo. Teriflunomide 7 mg significantly reduced ARR but not disability progression. Teriflunomide 14 mg significantly reduced annualized rates of severe relapse outcomes compared with TEMSO/TOWER by 20.5% (P = 0.0113/0.066; P = 0.0211); (B) 52.6% (P < 0.0001/0.0535; P = 0.0004); (C) 38.5% (P = 0.0286/0.525; P = 0.0015); (D) 59.3% (P < 0.0001/33.6%; P = 0.0155); and (E) 33.7% (P < 0.0003/35.7%; P = 0.0002). Teriflunomide 14 mg also significantly reduced annualized rates of severe relapse outcomes compared with TEMSO/TOWER by 20.5% (P = 0.0113/0.066; P = 0.0211); (B) 52.6% (P < 0.0001/0.0535; P = 0.0004); (C) 38.5% (P = 0.0286/0.525; P = 0.0015); (D) 59.3% (P < 0.0001/33.6%; P = 0.0155); and (E) 33.7% (P < 0.0003/35.7%; P = 0.0002). Teriflunomide 14 mg also significantly reduced annualized rates of severe relapse outcomes compared with TEMSO/TOWER by 20.5% (P = 0.0113/0.066; P = 0.0211); (B) 52.6% (P < 0.0001/0.0535; P = 0.0004); (C) 38.5% (P = 0.0286/0.525; P = 0.0015); (D) 59.3% (P < 0.0001/33.6%; P = 0.0155); and (E) 33.7% (P < 0.0003/35.7%; P = 0.0002). Teriflunomide 14 mg also significantly reduced annualized rates of severe relapse outcomes compared with TEMSO/TOWER by 20.5% (P = 0.0113/0.066; P = 0.0211); (B) 52.6% (P < 0.0001/0.0535; P = 0.0004); (C) 38.5% (P = 0.0286/0.525; P = 0.0015); (D) 59.3% (P < 0.0001/33.6%; P = 0.0155); and (E) 33.7% (P < 0.0003/35.7%; P = 0.0002). Teriflunomide 14 mg also significantly reduced annualized rates of severe relapse outcomes compared with TEMSO/TOWER by 20.5% (P = 0.0113/0.066; P = 0.0211); (B) 52.6% (P < 0.0001/0.0535; P = 0.0004); (C) 38.5% (P = 0.0286/0.525; P = 0.0015); (D) 59.3% (P < 0.0001/33.6%; P = 0.0155); and (E) 33.7% (P < 0.0003/35.7%; P = 0.0002).