



Efficacy of Pregabalin for Pain Management Associated with Diabetic Peripheral Neuropathy in Type 1 or Type 2 Diabetes Mellitus Subjects

SCIENCE

[Abstracts](#)

Key Take-Away:

Pregabalin belongs to the class of anticonvulsants, which works by reducing the number of pain signals sent out by impaired nerves in the body. All the analyses of pain and sleep scores (MMRM and LOCF) in this study were significant at all time points for subjects with type 2 diabetes mellitus.

Introduction:

This study aimed to compare the efficacy and safety of pregabalin for painful diabetic peripheral neuropathy (pDPN) in type 1 (T1DM) or 2 diabetes mellitus (T2DM) subjects.

Methods:

The pooled data from 10 RCTs (pregabalin-treated T1DM and T2DM subjects with pDPN) were examined for change from baseline (CFB) scores (pain and sleep disturbance) via the mixed model repeated measures (MMRM) through Week 12 and the last observation carried forward (LOCF). Adverse events (AEs) were recorded.

Results:

Pregabalin-treated (T1DM 156 [8.7%]; T2DM 1632 [91.3%]) and placebo subjects (T1DM 92 [9.6%]; T2DM 868 [90.4%]) had comparable baseline demographic characteristics between treatment groups within the same diabetes type. T2DM (vs T1DM) subjects were ~10 years older. With pregabalin and placebo, respectively, mean \pm SD baseline pain (T1DM: 6.2 ± 1.4 and 6.5 ± 1.6 ; T2DM: 6.5 ± 1.5 and 6.4 ± 1.5) and sleep scores (T1DM: 5.2 ± 2.4 and 5.2 ± 2.7 ; T2DM: 5.3 ± 2.5 and 5.1 ± 2.5) were comparable. Using MMRM, mean CFB treatment differences (pregabalin minus placebo) were significantly different for pain and sleep with either diabetes types (all weeks $p < .05$). With LOCF, pregabalin's odds ratios (ORs) of achieving 30% pain reduction were similar with T2DM (OR, 1.91, 95% CI [1.61, 2.27]) and T1DM (2.01 [1.18, 3.44]) (both $p \leq .01$). Pregabalin's ORs of 30% improvement in sleep quality was 1.81 (95% CI, 1.06, 3.09) with T1DM and 2.01 (1.69, 2.39) with T2DM (both $p < .05$). AEs were consistent with the known safety profile of pregabalin.

Conclusions:

Pregabalin significantly improved pain and sleep quality, without a clinically meaningful difference between diabetes types.

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Therapeutic, Pregabalin, Diabetic peripheral neuropathy, Anticonvulsant, Antiepileptic, Efficacy, Safety, Mixed model repeated measures (MMRM), Last observation carried forward (LOCF)