# Tolerability, Safety, and Quality of Life with Tapentadol Prolonged Release (PR) Compared with Oxycodone/Naloxone PR in Patients with Severe Chronic Low Back Pain with a Neuropathic Component: A Randomized, Controlled, Open-label, Phase 3b/4 Trial

**Article** *in* Pain Practice 16(5) · November 2015
DOI: 10.1111/papr.12361

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**Abstract**

Objective:
To evaluate tolerability, safety, and quality-of-life outcomes in non-opioid-pretreated patients with severe chronic low back pain with a neuropathic component receiving tapentadol PR vs. oxycodone/naloxone PR.

Methods:
Eligible patients (average pain intensity [numerical rating scale] ≥ 6; painDETECT positive/unclear ratings) were randomized to twice-daily tapentadol PR 50 mg or oxycodone/naloxone PR 10 mg/5 mg. After a 21-day titration (maximum twice-daily doses: tapentadol PR 250 mg, or oxycodone/naloxone PR 40 mg/20 mg plus oxycodone PR 10 mg), target doses were continued for 9 weeks. Change in the Patient Assessment of Constipation Symptoms (PAC-SYM) total score from baseline to final evaluation was a primary endpoint.

Results:
For the primary tolerability-related endpoint, the 97.5% exact repeated confidence interval for tapentadol PR minus oxycodone/naloxone PR for the PAC-SYM total score was [-0.259, 0.121], showing noninferiority (upper limit < 0.7). Incidences of constipation and vomiting were significantly lower with tapentadol PR than oxycodone/naloxone PR (P ≤ 0.045). Confirmatory superiority based on formal noninferiority was shown for the primary effectiveness endpoint (change from baseline to final evaluation in pain intensity) for tapentadol PR vs. oxycodone/naloxone PR (presented separately). Improvements in the Short Form-12 physical component summary and EuroQol-5 Dimension health status index and health state assessment were significantly greater with tapentadol PR vs. oxycodone/naloxone PR (P ≤ 0.024).

Conclusions:
Tapentadol PR had a minimal impact on bowel function (noninferior to oxycodone/naloxone PR) and, along with superior effectiveness (presented separately), was associated with significantly lower incidences of constipation and vomiting and significant improvements in quality-of-life measures vs. oxycodone/naloxone PR.

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