

Safety and Efficacy of Oxymorphone Extended Release for Patients With Chronic Low Back Pain and Hypertension, Diabetes, or Cardiovascular Disease

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Purpose

Evaluate the safety and efficacy of oxymorphone extended release (ER) in patients with comorbidities of hypertension, diabetes, and cardiovascular disease.

Method

This post hoc subanalysis evaluated pooled data from 2 multicenter, enriched-enrollment, randomized-withdrawal trials of oxymorphone ER in opioid-naïve and opioid-experienced patients with moderate to severe chronic low back pain (CLBP). Both trials included an open-label titration phase and a randomized, double-blind, 12-week treatment phase with oxymorphone ER and placebo. Patients entered the double-blind treatment phase if successfully titrated to a stable dose of oxymorphone ER that provided adequate pain relief (pain ≤ 40 mm on a 100-mm Visual Analog Scale [VAS]) and good tolerability. Adverse events (AEs) were monitored throughout the study, and patients assessed average VAS pain intensity during the past 24 hours at each clinic visit. Outcomes for this subanalysis were treatment-emergent AEs during open-label titration and double-blind treatment and change from baseline in VAS pain intensity during double-blind treatment. Outcomes were compared between comorbidity subgroups using descriptive statistics or the Fisher exact test.

Results

348 of 575 patients were successfully titrated to an effective and generally well-tolerated dose of oxymorphone ER (median stabilized dose, 40 mg in all comorbidity subgroups). During open-label titration, the proportion of patients reporting ≥ 1 AE was similar in subgroups with and without hypertension (69.1% [n=141/204] vs 69.3% [n=257/371], respectively), diabetes (73.8% [n=48/65] vs 68.6% [n=350/510]), and cardiovascular disease (73.8% [n=59/80] vs 68.5% [n=339/495]). During double-blind treatment with oxymorphone ER at the stabilized dose, reporting of ≥ 1 AE was similar in patients with and without diabetes (56.5% [n=13/23] vs 52.0% [n=79/152]) and hypertension (58.5% [n=38/65] vs 49.1% [n=54/110]); in the cardiovascular disease subgroup, reporting was more frequent in patients with vs without disease (72.7% [n=16/22] vs 49.7% [n=76/153]; $P=0.04$), that was largely due to an increase in nausea (22.7% [n=5/22] vs 5.9% [n=9/153]). Irrespective of comorbidity, the most frequent treatment-emergent AEs included nausea, constipation, somnolence, headache, diarrhea, and vomiting. During double-blind treatment with placebo, there was an increase from baseline to final visit in mean (SD) VAS pain intensity in patients with and without hypertension (27.9 [29.8] vs 28.4 [26.7]), diabetes (26.6 [30.5] vs 28.4 [27.4]), and cardiovascular disease (30.3 [26.2] vs 28.0 [27.8]). During double-blind treatment with oxymorphone ER, only small increases in mean (SD) VAS pain intensity were observed in patients with and without hypertension (9.8 [22.1] vs 9.6 [23.7]), diabetes (13.3 [25.0] vs 9.2 [22.8]), and cardiovascular disease (13.0 [24.5] vs 9.2 [22.9]).

Conclusions

Published trials have demonstrated oxymorphone ER to be effective and generally well tolerated in opioid-naïve and opioid-experienced patients with CLBP (Hale. *J Pain*. 2007;8[2]:175-184 and Katz. *Cur Med Res Opin*. 2007;23[1]:1170-128). Results of this post hoc subanalysis indicate similar efficacy and tolerability in patients with CLBP with and without hypertension, diabetes, and cardiovascular disease.