A posthoc pooled data analysis to evaluate the gastrointestinal tolerability profile of tapentadol extended release (ER) vs oxycodone controlled release (CR) in patients ≥75 years of age

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Purpose

This posthoc analysis evaluated analgesic efficacy and tolerability of tapentadol ER (100-250 mg bid) vs oxycodone HCl CR (20-50 mg bid) in patients ≥75 years of age (tapentadol ER, n=72; oxycodone CR, n=78) using pooled data from 3 similarly-designed 15-week, randomized, double-blind, placebo- and active-controlled, phase 3 studies of tapentadol ER for moderate-to-severe chronic osteoarthritis knee (NCT00421928, NCT00486811) or low back (NCT00449176) pain.

Method

Analgesic efficacy was determined by the change in pain intensity (11-point numerical rating scale). Times to initial onset of gastrointestinal TEAEs and time to study discontinuation due to these TEAEs were estimated using Kaplan-Meier plots.

Results

No significant between-treatment difference in the least-squares mean (SEM) change in pain intensity from baseline to week 15 was observed (tapentadol ER, -3.66[0.44]; oxycodone CR, -4.02[0.54]; P=.604). Significantly lower percentages of patients who received tapentadol ER vs oxycodone CR reported gastrointestinal TEAEs (51.4% vs 71.8%; P=.0119) and study discontinuations due to gastrointestinal TEAEs (16.7% vs 42.3%; P=.0007). Times to initial onsets of nausea, vomiting, and constipation and times to study discontinuation due to nausea and vomiting occurred later with tapentadol ER vs oxycodone CR (all P≤.0388; time to discontinuation due to constipation, P=.4685). Patients experienced the following common opioid-related gastrointestinal TEAEs for lower mean percentages of study days with tapentadol ER vs oxycodone CR, respectively: nausea, 10.2% vs 20.2%, P=.0621; vomiting, 1.6% vs 9.1%, P=.0008; constipation, 12.0% vs 24.8%, P=.1144.

Conclusions

Severity ratings of the common opioid-related gastrointestinal TEAEs (nausea, vomiting, constipation, and nausea and/or vomiting) were generally lower with tapentadol ER vs oxycodone CR. Tapentadol ER (100-250 mg bid) was associated with comparable analgesia and better gastrointestinal tolerability than oxycodone HCl CR (20-50 mg bid), including lower incidences of gastrointestinal TEAEs and study discontinuation due to gastrointestinal TEAEs, in patients ≥75 years of age.