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Curr Med Res Opin. 2009 May;25(5):1095-104. doi: 10.1185/03007990902816970 .



Tolerability of tapentadol immediate release in patients with lower back pain or osteoarthritis of the hip or knee over 90 days: a randomized, double-blind study.

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Abstract

OBJECTIVE: Tapentadol is a novel, centrally acting analgesic with two mechanisms of action, mu-opioid receptor agonism and norepinephrine reuptake inhibition, in a single molecule. This phase III, randomized, double-blind, active-controlled study evaluated the tolerability of tapentadol immediate release (IR) and oxycodone IR for low back pain or osteoarthritis pain (hip or knee), using flexible dosing over 90 days.

METHODS: Patients (N = 878) were randomly assigned (4:1 ratio) to receive tapentadol IR (50 or 100 mg, q4-6h, p.o.) or oxycodone IR (10 or 15 mg, q4-6h, p.o.). Tapentadol IR was evaluated for tolerability over 90 days, tolerability relative to oxycodone IR, withdrawal symptoms, and pain intensity. This study was not placebo-controlled, which limited efficacy evaluations.

RESULTS: In total, 849 intent-to-treat patients received tapentadol IR (n = 679) or oxycodone IR (n = 170), and among these, 391 patients (57.6%) in the tapentadol IR group and 86 patients (50.6%) in the oxycodone IR group completed the study. Gastrointestinal events, including nausea (18.4% vs 29.4%), vomiting (16.9% vs 30.0%), and constipation (12.8% vs 27.1%), were reported by 44.2% of patients receiving tapentadol IR and 63.5% of patients receiving oxycodone IR, respectively. Nervous system events, including dizziness (18.1% vs 17.1%), headache (11.5% vs 10.0%), and somnolence (10.2% vs 9.4%), were reported by 36.7% of patients receiving tapentadol and 37.1% of patients receiving oxycodone, respectively. Odds ratios (tapentadol:oxycodone) showed that the incidences of somnolence and dizziness were similar; however, nausea, vomiting, and constipation were significantly less likely with tapentadol IR compared with oxycodone IR. The pattern of withdrawal symptoms suggests that drug tapering may not be necessary after tapentadol IR treatment of this duration. Pain intensity measurements showed similar efficacy for tapentadol and oxycodone.

CONCLUSION: During this 90-day study, tapentadol IR was associated with improved gastrointestinal tolerability compared with oxycodone IR while providing similar pain relief. Trial registration information: [NCT00364546](#).

PMID: [19301989](#) DOI: [10.1185/03007990902816970](#)

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