
Citron ML¹, Kaplan R, Parris WC, Croghan MK, Herbst LH, Rosenbluth RJ, Reder RF, Slagle NS, Buckley BJ, Kaiko RF.

Author information

- ¹ProHealth Care Associates, LLP Lake Success, New York, USA.

Abstract

We conducted a study of the safety of controlled-release (CR) oxycodone tablets (OxyContin Tablets) administered chronically to patients with cancer-related pain in a usual clinical setting. These patients had participated in 1 of 2 double-blind, active-control studies. Our study was an open, 3-month treatment study that included 87 patients. Patients received CR oxycodone tablets every 12 hr in a manner that reflected typical clinical practice. Supplemental immediate-release (IR) oxycodone was available PRN for breakthrough pain. Patients recorded medication use, adverse events, and evaluations of pain intensity and acceptability of therapy in a daily diary. Forty-four patients (51%) completed all 12 weeks of study; 43 patients (49%) discontinued participation. At baseline and throughout the study period, the overall mean pain-intensity score was slight to moderate. A comparison of initial and final doses showed a significant but modest increase in total daily CR oxycodone dose. An increase or decrease in titration of the oxycodone dose occurred for 66 patients (84%) at least once during the 12-week study period, primarily for increased pain. Forty-four patients (56%) did not undergo dose titration when the latter was indicated. Half of the patients used IR oxycodone rescue almost daily; the mean number of rescue doses per day was 1.5. Despite stable pain control and an increasing total daily CR oxycodone dose, the percentage of patients reporting common opioid-related adverse events decreased over the course of the study. CR oxycodone tablets administered every 12 hr were successfully used to manage cancer pain over a 12-week period. Importantly, side effects diminished over time without a concomitant change in efficacy.

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