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## Clinical effectiveness and safety of OROS® hydromorphone in break-through cancer pain treatment: a multicenter, prospective, open-label study in Korean patients.

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### Author information

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### Abstract

**OBJECTIVE:** To evaluate the effectiveness of OROS® hydromorphone in reducing breakthrough pain (BTP) medication frequency in Korean patients with chronic cancer pain.

**SETTINGS AND DESIGN:** Multicenter, prospective, open-label, phase IV study.

**PARTICIPANTS:** Patients with chronic malignant pain using immediate-release oxycodone more than two times per day for BTP.

**INTERVENTIONS:** Patients were stabilized on their ongoing drug for 3 days immediately before baseline measurements (day 0). Medication was changed to OROS® hydromorphone at a dose equianalgesic to oxycodone using a 2.5:1 controlled-release oxycodone to hydromorphone hydrochloride conversion ratio; the patients were observed for 7 days. Dose was titrated, if required, and the patients were observed for another 7 days. Effectiveness and safety parameters were measured at baseline, day 7, and day 14.

**MAIN OUTCOMES:** BTP medication frequency on days 7 and 14, compared to baseline.

**RESULTS:** Of the 141 patients screened, 114 received study drug and 98 completed the study. Compared to day 0, daily BTP medication frequency on day 14 decreased from 2.93 to 2.00 ( $p > 0.0001$ ), daily BTP frequency decreased from 3.67 to 2.44 ( $p > 0.0001$ ), and end-of-dose pain frequency decreased by 44 percent. Pain was controlled adequately during daytime and nighttime. Pain intensity decreased by 11 percent as assessed using the Korean Brief Pain Inventory and by 17 percent as assessed using the numerical rating scale. About 61.2 percent patients and 60.2 percent physicians were satisfied with the treatment. Common adverse events, which occurred in 91.2 percent patients, were constipation, somnolence, and dizziness.

**CONCLUSION:** Once-daily OROS® hydromorphone is efficient in the reduction of cancer pain-related BTP episodes, including end-of-dose pain.

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