

Safety and efficacy of once-daily hydromorphone ER (OROS hydromorphone ER) compared with twice-daily oxycodone CR over 52 weeks in patients with moderate to severe chronic noncancer pain

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Purpose

Once-daily hydromorphone ER (OROS[®] hydromorphone ER) and oxycodone CR are semisynthetic, extended-release opioid analgesics with established efficacy. An open-label, randomized, 24-week, flexible-dose study demonstrated noninferiority of OROS hydromorphone ER vs oxycodone CR twice-daily for treatment of chronic noncancer pain.

Method

A total of 112 patients (60 OROS hydromorphone ER, 52 oxycodone CR; mean age, 58.1 y; 54% female; 100% Caucasian) with chronic noncancer pain who completed the previously published core-phase study were enrolled in a 28-week, open-label extension study. In the core phase (24 weeks), treatment was initiated with 8 mg OROS hydromorphone ER once daily or 10 mg oxycodone CR twice daily, followed by individual titration over 4 weeks to a maximum daily dose of 32 mg OROS hydromorphone ER or 80 mg oxycodone CR. In the 28-week extension phase, patients continued their regimens of OROS hydromorphone ER or oxycodone CR until week 52 or discontinuation. The primary efficacy measure in the extension phase was change in Brief Pain Inventory (BPI) item "pain right now," assessed at weeks 38 and 52. Global assessments of efficacy, dosing convenience, and tolerability were secondary endpoints.

Results

Mean change in pain assessment from baseline to week 38 was -3.0 (OROS hydromorphone ER) vs -2.8 (oxycodone CR), and from baseline to the end of the extension phase was -2.9 vs -2.8; these changes were similar to those observed in the core phase (-3.0 vs -3.3). After 52 weeks, global assessment of efficacy was rated as "very good" or "good" in the majority of patients who entered the extension phase (OROS hydromorphone ER, n=55 [91.7%]; oxycodone CR, n=45 [86.5%]). More patients in the OROS hydromorphone ER group (n=21 [35.0%]) vs the oxycodone CR group (n=11 [21.2%]) assessed mode of drug intake as "very convenient." The majority of patients receiving OROS hydromorphone ER (88.3%) and oxycodone CR (88.5%) rated tolerability as "good" or "very good" at 52 weeks, with few patients discontinuing due to an adverse event (1.6% vs 0.4%).

Conclusions

This extension study demonstrated that the effectiveness of OROS hydromorphone ER and oxycodone CR was maintained through 1 year. Changes in efficacy endpoints from baseline to week 38 and to the endpoint of the extension phase were generally comparable to the changes reported from baseline to the endpoint of the core phase.