A Randomized, Double-Blind Study Evaluating Conversion From Hydrocodone (HCD)/acetaminophen (Vicodin®) to Buprenorphine Transdermal System (BTDS) in Patients With Osteoarthritis Pain

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Purpose

Some of the challenges involved with opioid treatment of pain include loss of therapeutic effect, tolerability, and development of hyperalgesia. Opioid rotation is one treatment option to overcome these challenges. Physicians require guidance on conversion from patients’ existing opioid regimen to a new opioid formulation. This multicenter, randomized, double-blind, double-dummy, parallel-group study evaluated the efficacy and safety of converting patients with osteoarthritis (OA) pain from a stable regimen of oral HCD/acetaminophen to a 7-day BTDS.

Method

Adult patients with OA receiving a stable dosage of HCD 15-30 mg/day were switched to the nearest equivalent dosage of open-label Vicodin® for 7 days. Patients maintaining acceptable analgesia were stratified based on their Vicodin dosage and randomized to receive either titratable BTDS 10 mcg/hour (BTDS 10) or fixed-dose BTDS 20 mcg/hour (BTDS 20). The primary efficacy variable was completion of the 14-day double-blind phase. Additional exploratory variables included proportion of days of successful analgesia, rate of discontinuation, pain assessment, function and sleep indices, and patient treatment satisfaction. Safety and tolerability were assessed.

Results

A total of 18% of patients in the double-blind period discontinued, primarily for adverse events. Of 198 patients in the full analysis population, 167 (84.3%; 95% CI, 79.3-89.4) completed the 14-day double-blind phase, and the average proportion of days with successful analgesia was 74%. Average pain, function, and sleep quality were similar at the end of the run-in period, when patients were receiving Vicodin, and at end of the double-blind phase, when patients were receiving BTDS. Overall, patients preferred BTDS (85%) compared to their incoming oral Vicodin regimen. Adverse events were those typically associated with opioid analgesics and with transdermal administration. Patients randomized to BTDS 10 experienced slightly better tolerability compared with patients randomized to BTDS 20.

Conclusions

In this study, patients with OA pain were converted from Vicodin® to BTDS. Conversion to low initial doses of BTDS may improve overall tolerability.