58

Fentanyl Buccal Tablet Compared with Immediate-Release Oxycodone for the Management of Breakthrough Pain in Opioid-Tolerant Patients With Chronic Pain: Patient Disposition and Dose Titration

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Purpose

Data show that the effective dose of a rapid-onset, transmucosal opioid for breakthrough pain (BTP) is not related to the around-the-clock dose (ATC) of the drug. No data exist, however, on more traditional, short-acting oral opioids.

Method

In a head-to-head, 46-center study comparing fentanyl buccal tablet (FBT) with immediate-release oxycodone (OxyIR) for BTP, opioid-tolerant patients titrated FBT and OxyIR to a successful dose that provided adequate analgesia without unacceptable adverse events during 2 randomized, open-label periods. The doses of FBT (200, 400, 600, 800 µg) and OxyIR (15, 30, 45, 60 mg) were selected based on the relative potency estimate that FBT 100 µg is equivalent to OxyIR 7.5 mg. Efficacy was evaluated during 2 subsequent randomized, crossover, double-blind, double-dummy treatment periods.

Results

320 patients received treatment; 203 found a successful dose of both drugs and 183 were evaluable for efficacy. During the titration periods, 60 patients discontinued while receiving FBT and 69 while receiving OxyIR. Reasons for discontinuation were similar between treatments. 162/320 (51%) patients reported adverse events, which were similar between treatments. There was no linear relationship between the successful dose of FBT or OxyIR and the ATC opioid dose. The successful doses of FBT and OxyIR exhibited a strong concordance, as measured by Kendall's tau statistic (tau=0.62; $P<0.0001$). Of the patients who entered the study taking OxyIR and identified a successful dose of each drug, 78 of 96 (81%) titrated to a higher dose of OxyIR than was used at study entry.

Conclusions

The titrated, successful dose of OxyIR for BTP was not predicted by the ATC opioid dose. However, the successful dose of OxyIR was concordant with a dose of FBT estimated to be equivalent. The tolerability profiles were similar.