Aberrant drug-related behavior observed during a 12-week open-label study involving patients taking chronic opioid therapy for persistent pain and fentanyl buccal tablet or traditional short-acting opioid for breakthrough pain

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Purpose

Additional information on aberrant drug-related behavior during opioid therapy is needed. This study was designed to evaluate and compare the occurrences of aberrant drug-related behaviors between patients taking fentanyl buccal tablet (FBT) and patients taking other oral short-acting opioids (SAOs) to treat breakthrough pain (BTP) over 12 weeks of open-label treatment.

Method

Patients with chronic pain, including BTP, taking ≥60 mg/day of oral morphine or equivalent for persistent pain who completed the initial randomized, double-blind, crossover portion of the study were rerandomized to FBT or any traditional SAO for 12 weeks of open-label treatment. Patients with a recent history (≤5 years) of substance abuse were excluded from the study. Patients completed the Revised Screener and Opioid Assessment for Patients with Pain (SOAPP-R) at baseline and the Addiction Behaviors Checklist (ABC) and Current Opioid Misuse Measure (COMMTM) at final visit. Data from case report forms were also reviewed retrospectively and aberrant behaviors (defined as drug-seeking behavior and/or problematic narcotic use that may predict addictive disease) were identified.

Results

A total of 130 patients entered the open-label period and received treatment (65 received FBT and 65 received SAO [68% received oxycodone]). Baseline SOAPP-R scores were ≥18 for 19 (29%) patients in the FBT group and 15 (23%) patients in the SAO group. At final visit, ABC scores were ≥3 for 3 (5%) patients in the FBT group and 2 (3%) patients in the SAO group (P=.6). COMM scores were ≥9 for 9 (14%) patients in the FBT group and 5 (8%) patients in the SAO group (P=.3). Aberrant behaviors were identified in 12 (18%) patients in the FBT group and 13 (20%) patients in the SAO group. Of the patients with baseline SOAPP-R scores ≥18, 1 of 19 (5%) receiving FBT and 1 of 15 (7%) receiving SAO had ABC scores ≥3 at final visit (P=.9); 5 of 19 (26%) patients receiving FBT and 2 of 15 (13%) patients receiving SAO had COMM scores ≥9 (P=.3).

Conclusions

In this population of patients under structured care who were taking opioids for chronic pain, including breakthrough pain, the incidence of aberrant drug-related behaviors was statistically similar between patients taking fentanyl buccal tablet and any traditional short-acting opioids for breakthrough pain, even among patients who were at higher risk at baseline.