

## **Journal Watch (August 6, 2012)**

### **Sublingual fentanyl orally disintegrating tablet in daily practice: efficacy, safety and tolerability in patients with breakthrough cancer pain.**

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Reference: Überall MA, Müller-Schwefe GH. *Curr Med Res Opin.* 2011 Jul;27(7):1385-94. Epub 2011 May 11.

#### **Abstract**

##### **BACKGROUND AND OBJECTIVES:**

Breakthrough cancer pain (BTcP) affects more than half of patients with cancer pain and has severe detrimental impacts on quality of life (QoL). This study evaluated the efficacy, QoL impact and safety of sublingual fentanyl orally disintegrating tablet (sublingual fentanyl ODT), for the treatment of BTcP in a clinical setting.

##### **RESEARCH DESIGN AND METHODS:**

This was a prospective, multi-center phase IV study. Opioid-tolerant adult patients with BTcP received sublingual fentanyl ODT in the course of routine clinical practice, and completed questionnaires over a 28-day observation period. Efficacy was assessed using measures of maximum BTcP intensity and the times to first effect and maximum effect of sublingual fentanyl ODT. Changes in QoL were evaluated using the modified pain disability index (mPDI) and the hospital anxiety and depression scale (HADS). Adverse events were recorded throughout.

##### **RESULTS:**

Of 217 enrolled patients, 181 (83.4%) completed the observation period. During the study, 3163 episodes were treated with a mean dose of 401.4 µg per episode. The study recorded a significant improvement in maximum BTcP intensity with sublingual fentanyl ODT, compared with baseline ( $p < 0.0001$ ). Patients reported experiencing the first effects of the study drug within 5 minutes of administration in 67.7% of episodes, and maximum effect within 30 minutes in 63.2% of episodes. mPDI and HADS scores significantly improved during the observation period ( $p < 0.0001$ ). Sublingual fentanyl ODT was well-tolerated, with 12 patients (5.5%) experiencing  $\geq 1$  study drug-related adverse event. Study limitations include a modest size and duration, and the single-arm design.

##### **CONCLUSIONS:**

Under the conditions of a phase IV study, sublingual fentanyl ODT was effective and well-tolerated for the treatment of BTcP in opioid-tolerant cancer patients. Study treatment was associated with significant improvements in BTcP intensity and QoL scores, and patients reported rapid onset of action in the majority of episodes.

**Strengths**

Focuses specifically on breakthrough cancer pain-all patients were receiving oral opioids prior to study

High number of patients completed the study (83.4%)

High percentage of patients finds it better than what they used before (>80%)

High percentage of patients continued to take sublingual fentanyl ODT after the study ends (84.0%)

**Weakness**

Small sample size (only 217 patients)

Shorter duration (only 28 days)

Open label study - lack of control and randomization

Funded by the company that produces the medication

**Relevance**

Sublingual fentanyl orally disintegrating tablet (Abstral) appears to be effective in breakthrough cancer pain in opioid tolerant patients. It is fast acting, easy to take, and effective in terms of pain control and quality of life. It can be an alternative medication for use in breakthrough cancer pain. A larger, randomized-controlled trial of sublingual fentanyl ODT in the future would give us stronger evidence for its use.