Journal Watch

Aberrant Drug-Related Behavior Observed During Clinical Studies Involving Patients Taking Chronic Opioid Therapy for Persistent Pain and Fentanyl Buccal Tablet for Breakthrough Pain

Steven D. Passik, PhD, John Messina, PharmD, Anthony Golsorkhi, MD, et al.
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Memorial Sloan-Kettering Cancer Center (S.D.P.), New York, New York; and Cephalon, Inc.(J.M., A.G., F.X.), Frazer, Pennsylvania, USA

Prepared by: Yoko Tarumi, M.D.

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Abstract:

Context: Information on aberrant drug-related behaviors in the clinical study setting is limited.

Objective: This retrospective analysis was designed to identify the types and frequency of aberrant drug-related behaviors (including misuse and abuse) and associated patient characteristics in opioid-tolerant patients with chronic pain.

Methods: Data from opioid-tolerant patients participating in clinical studies of fentanyl buccal tablet (FBT) for breakthrough pain (up to 18 months of clinical study case-report forms) were retrospectively reviewed and coded for abuse, overdose, and aberrant behavior. Aberrant behaviors were categorized as those involving FBT (overuse, lost or stolen study drug) and those not involving FBT (patients seeking prescriptions from other sources, not returning for follow-up).

Results: Of the 1,160 patients evaluated, 10 (<1%) patients had an abuse-related event, 18 (<2%) had a positive urine drug screening (nonprescribed drug or illicit substance), and 12 (1%) had an event consistent with opioid overdose; 124 (11%) had aberrant behaviors related to FBT, and 68 (6%) had aberrant behaviors that were not. Aberrant behaviors were more frequent in men (odds ratio [OR]: 1.5; 95% confidence interval [CI]: 1.1, 2.1; p<0.01), in patients 42 years or younger (OR: 2.5; 95% CI: 1.6, 4.0; P<0.01), and in patients 43 years to 49 years (OR: 1.9; 95% CI: 1.2, 3.1; P<0.01).

Conclusion: The incidence of drug abuse events and aberrant drug-related behaviors was relatively low, probably because of the implementation of universal precautions and the controlled clinical study setting. Even in this setting, events occurred, highlighting the limits of screening and the need for ongoing monitoring of aberrant behavior.

Comments:

Strength/Uniqueness:

1) Information regarding the risk of aberrant behaviour associated with the new rapid-acting formulations of fentanyl is extremely limited, yet this risk has been always considered to be high. This is one of few studies that have been published on this topic.

2) This article heightens clinician awareness of the risk of aberrant behaviour developing in patients with chronic pain treated with fentanyl sublingual tablets.

Weakness:

1) This is an ad hoc analysis of a retrospective study to understand the long term tolerability of the new rapid-acting fentanyl products. There are significant limitations in the availability of information due to the nature of the methodology.

2) Lack of an agreed definition and screening system for aberrant behaviour causes significant confusion in interpreting the data.

Relevance to Palliative Care:

The generalizability of this study into palliative care practice is somewhat limited due to the type of population i.e. chronic pain rather than life threatening illness. The lack of information regarding a consistent screening approach also limits the clinical usefulness of the findings.