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Fentanyl Buccal Tablet in Breakthrough Pain in Opioid-Tolerant Patients with Cancer

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The management of breakthrough pain has been an 'orphan' therapeutic area for several years. In the last decade, there has been a growing interest in developing technologies to provide fast analgesia, given that traditional oral opioids do not address the temporal characteristics of breakthrough pain.

Oral transmucosal fentanyl citrate, formulated as a solid drug matrix on a handle, has been shown to produce a faster onset and greater degree of pain relief than oral morphine or placebo in the management of breakthrough pain. Fentanyl buccal tablet (FBT) represents a further refinement of transmucosal technology. Fentanyl is more rapidly absorbed and its bioavailability is higher from FBT than from oral transmucosal fentanyl citrate, as shown by the differences in the maximum plasma concentration (C_{max}), the time to C_{max} and the area under the concentration-time curve. Because the speed and extent of analgesic onset are critical factors in the effective treatment of breakthrough pain, fentanyl delivery with effervescent FBT represents an important therapeutic opportunity.

Of interest, in studies of both FBT and oral transmucosal fentanyl citrate, a placebo effect overlapping active drug effects and a lack of proportionality with the daily opioid dosing have been found. These findings could be explained by the differences between baseline pain intensity and breakthrough pain peaks, and/or a spontaneous decrease in pain intensity, as frequently occurs for incident pain depending on a patient's activity.

In clinical practice, in addition to providing a shorter onset of analgesia, the FBT formulation is convenient, easy to use and does not require further intervention after drug dissolution. In contrast, self-administration of oral transmucosal fentanyl citrate unit requires patient discipline and focus, which may limit compliance, particularly in patients with weakness. On the other hand, experience with oral transmucosal fentanyl citrate suggests that the use of this product can be discontinued when sufficient analgesia is produced as the unit is easily removed from the mouth with the handle; such flexibility is not available with FBT administration.

The development of new, non-invasive technologies to deliver opioids with a fast onset of analgesia has had an impressive impact in the management of breakthrough pain. Further comparative studies with other therapeutic options will better define the role of FBT in the management of breakthrough pain in patients with cancer. ▲