



New Study Demonstrates Superiority Of Caldolor® Over IV Acetaminophen In Reduction Of Post-Surgical Pain And Opioid Use

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NASHVILLE, Tenn. (October 29, 2018) – Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX), a U.S. specialty pharmaceutical company, today announced the publication of a study, with supporting data, concluding that preemptive anesthesia with IV ibuprofen is superior when compared to IV acetaminophen in reducing post-surgical pain and opioid use. The clinical trial conducted at Tufts University School of Dental Medicine in Boston, Massachusetts, was published online in the Journal of Oral and Maxillofacial Surgery, October 15, 2018.

This randomized single blinded study, led by Archana Viswanath, BDS, MS, compared the preemptive analgesic effects of Caldolor® (IV ibuprofen) to Ofirmev® (IV acetaminophen) in controlling post-surgical pain and reliance on opioids or over-the-counter medication for rescue pain control. The study was conducted in subjects undergoing surgical extraction of two or more impacted third molars under deep sedation. Its aims were to evaluate pain control and determine any difference in the pain medications consumed post-operatively.

A total of fifty-three subjects were dosed in the randomized, single-blinded clinical study. Twenty-five patients were infused with 800 mg of Caldolor and twenty-eight patients were infused with 1,000 mg Ofirmev just prior to the procedure. At the 4-hour marker, study investigators found that patients pre-treated with Caldolor experienced significantly less pain than those treated with Ofirmev ($p=0.004$). This trend continued at both 24 hours ($p=0.019$) and 48 hours ($p=0.017$) post-surgery. With such a marked reduction in pain, subjects treated with Caldolor required significantly fewer rescue analgesics than patients pre-treated with Ofirmev ($p=0.005$).

According to the publication, the surgical removal of impacted wisdom teeth is one of the most common procedures performed in the field of oral and maxillofacial surgery. Approximately ten million wisdom teeth are extracted in the U.S. annually. Post-operative pain is a common problem, and pain management must be done effectively to reduce the likelihood of developing a state of chronic pain or addiction to opioids. Merely a history of opioid prescriptions increases the risk for overdose and opioid use disorder. Furthermore, the more opioid pills prescribed can result in unused pills available for misuse or overdose.

The study investigators concluded, based on their observations and objective measurements, that preemptive analgesia with IV ibuprofen is more effective than IV acetaminophen in reducing postoperative pain and opioid use in the model studied.