

PD-25. VALDECOXIB HAS SIMILAR EFFICACY TO OXYCODONE 10 MG/ACETAMINOPHEN 1000 MG IN REDUCING PAIN FOLLOWING ORAL SURGERY: RESULTS OF A RANDOMIZED, DOUBLE-BLIND, PLACEBO CONTROLLED TRIAL

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This study compared the analgesic efficacy and safety of the COX-2 specific inhibitor, valdecoxib, with oxycodone 10 mg/acetaminophen 1000 mg, in patients experiencing moderate-to-severe pain following extraction of two or more impacted third molars. A total of 201 patients were recruited into this double-blind, randomized study and received a single oral dose of valdecoxib (20 mg or 40 mg), oxycodone 10 mg/acetaminophen 1000 mg or placebo. Key efficacy variables included median time to onset of analgesia, time-specific pain intensity difference and pain relief over 24 hours, Time-weighted Sum of Total Pain Relief (TOTPAR), and time to rescue medication. Patients receiving either valdecoxib dose experienced a rapid onset of analgesia (median: 29-35 minutes), and an initial level of pain relief similar to oxycodone 10 mg/acetaminophen 1000 mg. All active treatments resulted in median time to onset and peak pain intensity difference (PPID) scores that were significantly greater than placebo, and similar to each other (table). Compared with oxycodone/acetaminophen, both doses of valdecoxib resulted in significantly longer times to rescue medication, suggesting that valdecoxib has a longer duration of analgesia than oxycodone/acetaminophen, which is typically administered every 6 hours as needed for pain. Both doses of valdecoxib were associated with significantly fewer opioid-type adverse events (nausea and dizziness) than oxycodone/acetaminophen, and there was no increase in the incidence of adverse events with increasing dose of valdecoxib. The novel COX-2 specific inhibitor, valdecoxib, at single doses of 20 or 40 mg, acts rapidly, providing similar onset and peak pain relief as oxycodone/acetaminophen following oral surgery, and sustains analgesia over 24 h, with superior tolerability compared to oxycodone/acetaminophen.

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| | Placebo | Oxycodone 10 mg/ acetaminophen 1000 mg | Valdecoxib 20 mg | Valdecoxib 40 mg |
|---|--------------|--|---------------------|------------------|
| Median time to onset (h:min) | > 24:00 | 00:29 ‡ | 00:29 ‡ | 00:35 ‡ |
| Median Time to Rescue Medication (h:min) | 1:04 | 6:04 § | 10:58 †§ | > 24:00 †§ |
| Mean TOTPAR-24 (SEM) | 13.96 (24.6) | 38.36 (24.6) ‡ | 50.87 (33.4)* ‡ | 55.98 (38.2)* ‡ |
| Mean PPID (SEM) | 0.45 (0.12) | 1.78 (0.12) ‡ | 1.78 (0.15) ‡ | 1.80 (0.16) ‡ |
| Overall AE rates (%) | 41.2 | 56.9 | 28.6 § | 32.0 § |
| Nausea (%) | 19.6 | 29.4 | 6.1 † | 10.0 † |
| Dizziness (%) | 5.9 | 27.4 § | 6.1 † | 6.0 † |
| Significantly different from oxycodone/acetaminophen at a level of *P < 0.001, † P < 0.05. Significantly different from placebo at a level of ‡ P < 0.001, § P < 0.05. | | | | |