ANALGESIC EFFECTIVENESS OF A NEW, EXTENDED-RELEASE IBUPROFEN IN POSTOPERATIVE DENTAL PAIN

Steven Christensen, DDS
Jean Brown Research, Oral Surgery

INTRODUCTION / AIM
Assess efficacy/safety of immediate-release/extended-release (IR/ER) ibuprofen (IBU) in dental pain.

METHODS
Single-centre, randomized, double-blind, placebo-controlled studies (Study 1: single dose, 24 hours; Study 2: multiple doses, 48 hours) enrolled subjects aged 16–40 with ≥ moderate pain following third molar extraction. Single doses of 2 IBU 600 mg IR/ER formulations (A or B), naproxen sodium 220 mg, or placebo (2:2:2:1 ratio) were administered in Study 1; 4 doses IBU 600 mg IR/ER or placebo (1:1 ratio) in Study 2. Primary efficacy: time-weighted sum of pain intensity differences (SPID; Study 1) or time-weighted sum of pain relief and pain intensity differences (SPRID; Study 2) from 0–12 and 8–12 hours.

RESULTS
Study 1 (N=196): mean (SD) SPID 0–12 scores were 16.87 (9.4), 17.34 (10.5), 12.66 (10.0), and 0.05 (9.2) and SPID 8–12 scores were 6.57 (4.4), 7.14 (5.2), 5.14 (5.0), and -0.03 (4.1) for IBU IR/ER A, IBU IR/ER B, naproxen, and placebo, respectively (P<0.001, each active vs placebo). Study 2 (N=106): mean (SD) SPRID 0–12 scores (41.5 [21.0] vs 18.2 [20.0]) and SPRID 8–12 scores (18.4 [12.1] vs 10.3 [12.0]) favoured IBU IR/ER over placebo (P<0.001 for both). Study 2 interval SPID scores over 48 hours favoured IBU IR/ER (P<0.05) except at 20–24 hours. More AEs occurred with placebo in Study 1 (P=0.045) and Study 2 (P=0.001); most commonly, gastrointestinal AEs. No serious AEs occurred.

DISCUSSION / CONCLUSIONS
IBU 600 mg IR/ER every 12 hours provided safe and effective analgesia following single or multiple doses.

OTHER AUTHORS
Suzanne Meeves, PharmD, MBA
Shyamalie Jayawardena, PhD
Stephen Daniels, DO
Edward Paluch, PhD, MBA

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