Randomized Double-Blind Trial Comparing 3 Doses Of Oral Ibuprofen For Management Of Acute Pain In Adult Emergency Department Patients.

Sergey Motov, MD; Aidin Masoudi, MD; Jefferson Drapkin, BS; Cecily Sotomayor, MD; Samuel Kim, MD; Mahlaqa Butt, BS; Antonios Likourezos, MA MPH; Catsim Fassassi, MD; Rukhsana Hossain, MPH; Jason Brady, PharmD; Nechama Rothberger, PharmD; Peter Flom, PhD*; John Marshall, MD - Maimonides Medical Center; *Peter Flom Consulting, New York

Objective: Ibuprofen is a widely used non-steroidal anti-inflammatory drug (NSAID) for management of acute pain in the Emergency Department (ED). The analgesic ceiling for ibuprofen is 200-400mg/dose, and about 1200mg/day. However, it's often used at doses above its analgesic ceiling (600-800mg/dose) in various clinical settings including ED's, which might increase the probability for adverse drug reactions after prolong use. We hypothesize that administration of oral ibuprofen in a dose of 400 mg is as effective as 600 mg and 800 mg in treating acute pain in patients presenting to the ED.

Methods: We conducted a randomized, double-blind trial comparing analgesic efficacy of 3 doses of oral ibuprofen (400 mg, 600 mg, and 800 mg) in adult patients presenting to the ED with a variety of acute painful conditions. We excluded patients with peptic ulcer disease, gastrointestinal hemorrhage, renal or hepatic insufficiency, allergies to non-steroidal anti-inflammatory drugs (NSAID’s), pregnancy/breastfeeding, and altered mental status. The primary outcome included a difference in pain scores between three groups at 60 minutes. Secondary outcomes included a comparative reduction in pain scores in each group from baseline to 60 minutes, rates of adverse events, and need for rescue analgesia at 60 minutes. We used ANOVA and Chi square tests for data analysis.

Results: We enrolled 225 subjects (75 per group). The demographic characteristics were similar for all three groups (p > 0.05). The mean NRS pain scores at baseline were 6.5, 6.4, and 6.5 (p=0.891) and improved to 4.4, 4.5, 4.5 (p=0.816) at 60 minutes for 400 mg, 600 mg, and 800 mg groups, respectively. The difference in mean pain scores at 60 minutes between 400 mg and 600 mg groups was -0.14 (95% CI: -0.67 to 0.39); between 400 mg and 800 mg groups was 0.14 (95% CI: -0.65 to 0.37); and between 600 mg and 800 mg groups was 0.00 (-0.47 to 0.47). The reduction in mean numeric rating scale pain scores were statistically significant from baseline to 60 minutes within each group: 2.1 (95% CI: 1.8 to 2.4) for 400 mg; 1.9 (95% CI: 1.7 to 2.0) for 600mg; and 2.0 (95% CI: 1.7 to 2.2) for 800 mg, respectively. No clinically concerning changes in vital signs were observed. There were no serious adverse events in each group.

Conclusion: Oral Ibuprofen has similar analgesic efficacy for short-term pain relief in adult ED patients presenting with acute pain at doses of 400, 600, and 800 mg.