Comparing Oral Ibuprofen And Acetaminophen To Either Medication Alone For Management Of Acute Pain In Pediatric Emergency Department.

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Objectives: Ibuprofen and Acetaminophen (APAP) are commonly used analgesics in the pediatric ED for management of acute traumatic and non-traumatic pain. However, the analgesic benefits of combination ibuprofen and acetaminophen in this specific setting do not exist, only in pediatric patients with postoperative pain. Our aim is to evaluate analgesic efficacy, safety and feasibility of combination therapy to potentially broaden its clinical application in the pediatric ED. We hypothesize that combination of oral ibuprofen and APAP is superior to either analgesic `alone and is an excellent analgesic modality for controlling acute traumatic/non-traumatic pain in the pediatric ED.

Methods: We conducted a prospective, randomized; double-blind trial evaluating ED patients aged 3-17 years with acute pain. Enrolled patients were randomized to three groups: Group 1: oral ibuprofen at 10mg/kg dose and placebo of equal volume; Group 2: oral APAP at 15 mg/kg dose and placebo of equal volume; and, Group 3: oral ibuprofen at 10 mg/kg dose and APAP at 15mg/kg dose. Analgesics were administered orally via pre-filled syringes of identical volume, color, and flavor. Pain scores were recorded on a standard Numeric Rating Scale (NRS) and Wong-Baker (FACES) Scale at baseline and 60 minutes. Primary outcome is the comparative reduction of pain via NRS/FACES pain scale at 60 minutes from administration of medication. Secondary outcomes include incidence and type of adverse events, need for rescue analgesia, and patients’ and parents’ satisfaction with achieved level of analgesia. Data were analyzed by intention-to-treat using frequency distributions, chi-square test, and ANOVA. Power analysis indicated a need for total enrollment of 90 patients.

Results: We enrolled 90 subjects (30 per group). The demographic characteristics were similar for all three groups (P>.05). The mean NRS pain scores at baseline were 5.1, 5.8, and 5.8 (p=0.316) and improved to 2.3, 3.0, 2.7 (p=0.549) at 60 minutes respectively. The difference in mean pain scores at 60 minutes between group 1 and group 2 was -0.63 (95% CI: -1.81 to 0.54); between group1 and group 3 was -0.33 (95% CI: -1.47 to 0.81); and between group 2 and group 3 was 0.29 (-0.84 to 1.43). The reduction in mean numeric rating scale pain scores were statistically significant from baseline to 60 minutes within each group: 2.8 (95% CI: 2.0 to 3.5) for group 1; 2.7 (95% CI: 1.9 to 3.5) for group 2; and 3.1 (95% CI: 2.4 to 3.8) for group 3, respectively. No clinically concerning changes in vital signs were observed. There were no serious adverse events in each group.

Conclusion: The combination of oral ibuprofen and APAP therapy is not superior to either drug alone for controlling acute traumatic/non-traumatic pain in the pediatric ED.