

Pain Outcomes of Intra-operative IV Tylenol and/or Toradol for Carpal Tunnel and Distal Radius Fracture Surgeries

NCT 02313675

Initial IRB approval: 5/11/15

Most recent IRB renewal: 1/25/17

This study was designed as a randomized, double-blind, placebo-controlled study. The study was approved by our local Institutional Review Board, PRO14110464. It was registered with Clinicaltrials.gov, NCT02313675. Patients were recruited from the clinical practice of the senior author and enrolled in the study if consented to undergo endoscopic carpal tunnel release. The following exclusion criteria were used: current pregnancy, allergy to acetaminophen or ketorolac; medical contraindication to acetaminophen and/or ketorolac; pre-operative/current use of opioids; history of IV drug abuse; workers' compensation.

The Investigational Drug Service (IDS) at our institution randomized subjects using a blocked computerized randomization protocol and dispensed the study medication. The four treatment arms include: placebo (Group 1), IV acetaminophen (Group 2), IV ketorolac (Group 3), or both IV acetaminophen and IV ketorolac (Group 4). The dose of ketorolac was 10 mg and the dose of acetaminophen was 1000 mg. Subjects and surgeon were blinded to the medication given as IDS will dispensed the medications in opaque syringes. The medications were given 5 minutes prior to skin incision.

All patients undergoing carpal tunnel release were treated according to the same standard protocol for anesthesia and pain control. Patients were placed under sedation by the anesthesiologist using a standard weight-based dose of propofol and maintained on light sedation using a standard weight-based titration of propofol. After adequate sedation, the senior author injected a mixture of 5 mL of 1% lidocaine and 5 mL of 0.5% marcaine into the surgical field for intra-operative procedural anesthesia. All carpal tunnel releases were performed using a single incision endoscopic technique.

All patients received the same standard post-operative prescriptions for pain management: Tylenol 1000 mg by mouth every 8 hours, naproxen 500 mg by mouth every 12 hours, and oxycodone 5 mg by mouth every 6 hours as needed for severe pain rated as more than 7 out of 10 on an 11-point pain scale (0-10). Each oxycodone prescription was for 20 tablets and no refills were authorized. Pain surveys were distributed to the subjects on the day of surgery and the subjects were instructed to complete the surveys every 8 hours for 7 days after surgery. The subjects also noted the number of oxycodone tablets consumed per day.