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Brief Reports

INTRAVENOUS LIDOCAINE FOR THE EMERGENCY DEPARTMENT TREATMENT OF ACUTE RADICULAR LOW BACK PAIN, A RANDOMIZED CONTROLLED TRIAL

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☐ **Abstract—Background: Acute radicular back pain is a frequent complaint of patients presenting to the Emergency Department. Study Objective: Determine the efficacy of intravenous lidocaine when compared to ketorolac for the treatment of acute radicular low back pain. Methods: Randomized double-blind study of 41 patients aged 18–55 years presenting with acute radicular low back pain. Patients were randomized to receive either 100 mg lidocaine or 30 mg ketorolac intravenously over 2 min. A 100-mm visual analog scale (VAS) was used to assess pain at Time 0 (baseline), and 20, 40, and 60 minutes. Changes in [median] VAS scores were compared over time (within groups) by the signed-rank test and between groups by the rank-sum test. A 5-point Pain Relief Scale (PRS) was administered at the conclusion of the study (60 min) and again at 1 week by telephone follow-up; [median] scores were compared between groups by rank-sum. Results: Forty-four patients were recruited; 41 completed the study (21 lidocaine, 20 ketorolac). Initial VAS scores were not significantly different between the lidocaine and ketorolac groups (83; 95% confidence interval [CI] 74–98 vs. 79; 95% CI 64–94; $p = 0.278$). Median VAS scores from baseline to 60 min significantly declined in both groups (lidocaine [8; 95% CI 0–23; $p = 0.003$]; ketorolac [14; 95% CI 0–28; $p = 0.007$]), with no significant difference in the degree of reduction between groups ($p = 0.835$). Rescue medication was required by 67% receiving lidocaine, compared to 50% receiving ketorolac. No significant change in PRS between groups was found at the conclusion or at the follow-up. Conclusion: Intravenous lidocaine failed to clinically alleviate the pain associated with acute radicular low back pain. Published by Elsevier Inc.**

☐ **Keywords—lidocaine; ketorolac; radicular; pain**

INTRODUCTION

Acute radicular back pain is a frequent complaint in the Emergency Department (ED) and is usually caused by nerve impingement or inflammation (1–3). It often presents as a shooting, electric pain that radiates into the buttocks or posterior thigh of patients and is described as an excruciating, lancinating pain that is often recalcitrant to available over-the-counter medications. The course of this neurogenic pain is persistent, with many relapses often affecting the patient's ability to play sports, work, or even ambulate (1–4).

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Multiple medications have been explored for the treatment of acute neuropathic low back pain, but few have made a clinically significant impact (5). Intravenous lidocaine in dose ranges from 1.5 to 5.0 mg/kg has been advocated for the reduction of various neurologic pain syndromes (6–12). Additionally, intravenous lidocaine has been reported to reduce the level of the neuropathic pain for 3–21 days after infusion (13). Our objective was to determine the efficacy of a one-time bolus administration of intravenous lidocaine on reducing the reported intensity of radicular back pain in patients presenting to the ED.

We chose to conduct a randomized clinical trial comparing intravenous lidocaine to intravenous ketorolac, a well-known and commonly prescribed non-steroidal anti-inflammatory medication.

METHODS

Study Design

This was a randomized controlled double-blinded study to evaluate the efficacy of intravenous lidocaine when compared to ketorolac for the ED treatment of acute radicular back pain. The medical center's institutional review board for protection of human subjects approved the study. Written informed consent was obtained from all participants and an investigational new drug application was filed with the United States Food and Drug Administration.

Study Setting and Population

The study was conducted in the ED of a tertiary care medical center that serves beneficiaries of active duty and retired military personnel and has an annual census of 65,000. A convenience sample of patients aged 15–55 years who presented with the complaint of radicular low back pain were eligible. Patients were recruited any time of the day based on the rotating scheduling of our research assistants.

Study Protocol

Patients were eligible for enrollment if they met criteria for radicular back pain that were defined as the acute onset of back pain that possessed a radicular component as determined by the treating physician. Patients were excluded if they were pregnant, had a fever $\geq$38.1°C (100.5°F), diastolic blood pressure of $\geq$105 mm Hg, or met any of the following criteria: medical history of peptic ulcer disease, renal insufficiency, structural or ischemic cardiac disease, or persistent neurological deficits. Patients with a history of allergic reactions to amide local anesthetics were also excluded, along with patients with an initial pain score of 25 mm or less on the 100-mm non-hatched visual analog scale (VAS).

After obtaining informed consent and a negative urine pregnancy test result for female patients, patients were asked by a research assistant to grade their baseline pain. After the baseline data were obtained, an intravenous line was placed and patients were prospectively randomized to receive intravenously either 100 mg lidocaine or 30 mg ketorolac over 2 min, followed by a 10-cc normal saline flush. Randomization was accomplished by the use of a computerized random numbers table. The study medication was coded and was drawn up in similar-appearing syringes and administered by a nurse who was not party to the study. Both the investigator and the patient remained blinded to the medication delivered until the code was broken at the close of enrollment.

After the infusion of the study medication, patients were asked to grade their pain on the VAS at 20-min intervals until Time 60 min without viewing previous scores. Neurologic adverse events were recorded by actively questioning all subjects about tingling, numbness, or drowsiness starting at 5 min after the medication infusion and continuing at 20-min intervals. Heart rate, respiratory rate, and pulse oximetry were continually monitored, and blood pressure was recorded every 5 min. Patients also underwent continuous three-lead electrocardiographic monitoring throughout the study.

The study concluded at Time 60 min. If the subject's radicular back pain was not sufficiently relieved by the study medication as reported by the patient, rescue therapy was instituted at the discretion of the treating physician, with the exception of the use of both study medications.

The patient's pain relief was also assessed at the conclusion of the study and 1 week after the conclusion using a Pain Relief Scale (PRS): 0 = worse pain, 1 = no change in pain, 2 = slight pain relief, 3 = moderate pain relief, 4 = a lot of pain relief, 5 = complete pain relief.

Data Analysis

Median VAS scores for pain were calculated and differences in VAS scores from Time 0 (baseline) to Time 60 min (conclusion of study) were compared across groups using Wilcoxon's signed-rank test and between groups using a rank-sum test. Data from the PRS were analyzed similarly. A Fisher's exact test of contingency compared numbers of patients rescued vs. not rescued against drug type. Stata 12.0 software (Stata Corp, College Station TX) was used for data analysis.

Sample Size Determination

Power analyses were based on *t*-tests of VAS differences because the data irregularity seen after data acquisition