

Original Contributions

PARENTERAL CORTICOSTEROIDS FOR EMERGENCY DEPARTMENT PATIENTS WITH NON-RADICULAR LOW BACK PAIN

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□ **Abstract**—Although not recommended for low back pain, the efficacy of systemic corticosteroids has never been evaluated in a general low back pain population. To test the efficacy of systemic corticosteroids for Emergency Department (ED) patients with low back pain, a randomized, double-blind, placebo-controlled trial of long-acting methylprednisolone was conducted with follow-up assessment 1 month after ED discharge. Patients with non-traumatic low back pain were included if their straight leg raise test was negative. The primary outcome was a comparison of the change in a numerical rating scale (NRS) 1 month after discharge. Of 87 subjects randomized, 86 were successfully followed to the 1-month endpoint. The change in NRS between discharge and 1 month differed between the two groups by 0.6 (95% confidence interval -1.0 to 2.2), a clinically and statistically insignificant difference. Disability, medication use, and healthcare resources utilized were comparable in both groups. Corticosteroids do not seem to benefit patients with acute non-radicular low back pain. © 2006 Elsevier Inc.

□ **Keywords**—Low back pain; emergency department; methylprednisolone

INTRODUCTION

Acute low back pain is common, frequently debilitating, and often causes morbidity weeks to months after an

initial visit to a health care provider (1,2). Traditional medical management is only moderately effective—despite standard treatments, up to 50% of low back pain patients have poor functional outcomes 2 to 4 weeks after a medical visit and as many as 79% of low back pain patients report persistent pain or functional limitations three months after a visit to a general practitioner (3–7). Research in the field is complicated by the fact that a heterogeneous group of injuries cause low back pain and that a specific etiology for an individual's back pain is rarely found (1). Multiple well-designed studies help a physician choose acute treatment for low back pain patients, but few medical treatments have demonstrated long-term benefit (8).

Although non-steroidal agents have clear benefit in low back pain patients, the role of corticosteroids is insufficiently understood (9). A guideline statement from the Agency for Health Care Policy and Research did not endorse the use of corticosteroids for low back pain, but found inadequate evidence to comment on the topic definitively (10). The only systemic corticosteroid clinical trials performed to date do not pertain to the average patient seen in an Emergency Department (ED) or a general practitioner's office due to referral bias, selection bias, and because standard treatment has changed over the two to three decades since those studies were performed (11–13).

Due to the evidence gap with regard to this potentially important treatment, and due to the poor prognosis of many low back pain patients, we tested the hypothesis that one dose of a long-acting parenteral corticosteroid would improve low back pain in a homogenous group of patients with acute non-radicular low back pain 1 month after discharge from an ED.

METHODS

Study Design

This was a randomized, double-blind placebo-controlled clinical trial evaluating intramuscular methylprednisolone acetate as adjunctive therapy for low back pain. This trial randomized subjects after they had been evaluated and treated in the ED and were ready for discharge. All subjects were followed-up by telephone call 1 week and 1 month after ED discharge. In addition to the corticosteroid or placebo injection, all subjects were given a complimentary 1-week supply of naproxen 500 mg tablets, oxycodone 5 mg/acetaminophen 325 tablets and a detailed low back pain instruction sheet. This study was approved by the Montefiore Medical Center institutional review board.

Setting

This study took place in the Bronx, New York at Montefiore Medical Center, the primary teaching hospital of the Albert Einstein College of Medicine. This ED sees 80,000 adult patients annually. Enrollment took place continuously between July 2003 and October 2004.

Selection of Participants

The attending emergency physician referred all adult patients (at least 21 years old) who presented with a chief complaint of non-traumatic low back pain during all ED operating hours. The department's research assistants (five trained, full-time employees) were responsible for enrolling the subjects under the supervision of the investigators. The research assistants determined eligibility using an explicit checklist containing detailed inclusion and exclusion criteria. When interviewing a subject, the research assistants employed this checklist in a predetermined, standardized fashion. Eligibility was confirmed by the principal investigator before unblinding. The research assistants included in this study any patient who had low back pain for less than 1 week and was 50 years of age or younger. Low back pain was described as pain

originating below the tips of the scapulae and above the buttocks. Due to the desire to maintain a homogeneous group of subjects who would represent the average low back pain patient, patients were included only if their straight leg raise test, as described below, was negative. Patients were included if their back pain was caused by a twisting or lifting mechanism but excluded if they had been in a motor vehicle collision, had experienced direct blunt trauma to the back, or if they had a fall from greater than 4 feet. Patients were also excluded if the emergency physician felt there was a high likelihood the patient had a secondary cause of low back pain, e.g., metastatic bone disease or infection. Patients were also excluded for temperature greater than 37.9°C (100.3°F), pregnancy, lactation, allergy to or intolerance of a study medication. Patients could only enroll once. Patients could not have had another episode of back pain within 4 weeks before the current back pain attack. Patients were excluded for systemic steroid use within 4 weeks, a history of back surgery, a neoplasia known to metastasize, a chronic pain syndrome, an inflammatory arthritis, and suspected vascular, urologic or gynecologic pathology.

Rationale for the Straight Leg Raise Test

Although the precise test characteristics of the straight leg raise test are unknown, a positive ipsilateral straight leg raise is a sensitive marker for a herniated intervertebral disc (14). Therefore, if this test is negative, it can help rule-out the disease. To maintain a homogeneous cohort, subjects were stratified based on results of the straight leg raise test. Many definitions of the straight leg raise test exist. To identify distinct populations, the research assistants were given a strictly defined, conservative definition of this test: namely, the test was considered positive if a subject had ipsilateral pain shooting below the knee when either leg was raised between 30 and 70 degrees, as measured with a protractor. Contralateral pain below the knee, considered more specific for a herniated disc, was also classified as a positive straight leg raising test and rendered patients ineligible for study entry (14).

Randomization and Blinding

Randomization was done by the pharmacist in blocks of six using computer-generated random number tables available online. In an order determined by these random number tables, the pharmacist inserted study medication or placebo into vials and placed these vials into sequentially numbered research bags. The research bags were then used in order by the research assistants. Assignment was known only by the

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