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PREDNISONE FOR EMERGENCY DEPARTMENT LOW BACK PAIN: A RANDOMIZED CONTROLLED TRIAL

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□ **Abstract—Background: Although oral corticosteroids are commonly given to emergency department (ED) patients with musculoskeletal low back pain (LBP), there is little evidence of benefit. Objective: To determine if a short course of oral corticosteroids benefits LBP ED patients. Methods: Design: Randomized, double-blind, placebo-controlled trial. Setting: Suburban New Jersey ED with 80,000 annual visits. Participants: 18–55-year-olds with moderately severe musculoskeletal LBP from a bending or twisting injury ≤ 2 days prior to presentation. Exclusion criteria were suspected nonmusculoskeletal etiology, direct trauma, motor deficits, and local occupational medicine program visits. Protocol: At ED discharge, patients were randomized to either 50 mg prednisone daily for 5 days or identical-appearing placebo. Patients were contacted after 5 days to assess pain on a 0–3 scale (none, mild, moderate, severe) as well as functional status. Results: The prednisone and placebo groups had similar demographics and initial and discharge ED pain scales. Of the 79 patients enrolled, 12 (15%) were lost to follow-up, leaving 32 and 35 patients in the prednisone and placebo arms, respectively. At follow-up, the two arms had similar pain on the 0–3 scale (absolute difference 0.2, 95% confidence interval [CI] −0.2, 0.6) and no statistically significant differences in resuming normal activities, returning to work, or days lost from work. More patients in the prednisone than in the placebo group sought additional medical treatment (40% vs. 18%, respectively, difference 22%, 95% CI 0, 43%). Conclusion: We detected no benefit from oral corticosteroids in our ED patients with musculoskeletal LBP.** © **2014 Elsevier Inc.**

□ **Keywords—low back pain; steroids; musculoskeletal pain**

INTRODUCTION

Low back pain (LBP) is a common medical problem with a lifetime incidence well over 50% (1). It accounts for as many as 139 million medical visits a year in the United States (US), of which 2.6 million take place in the emergency department (ED) (2–7). Some researchers distinguish between radicular and musculoskeletal LBP clinically, although there is likely considerable overlap between these entities (7–13). The ED treatment of LBP is predominantly supportive and not particularly effective (7). Most patients receive a combination of nonsteroidal antiinflammatory drugs, opioids, and muscle relaxants (2–6). In addition, approximately 5% receive corticosteroids despite the paucity of data supporting efficacy (6). Further, the evidence supporting this therapy for musculoskeletal, as opposed to radicular, LBP is even less convincing. Corticosteroids are commonly used for other painful and inflammatory conditions and have the

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advantages of long half-life, inexpensive cost, and diverse administration routes.

The objective of this study is to assess the efficacy of oral corticosteroids for the treatment of acute musculoskeletal LBP presenting to an ED.

MATERIALS AND METHODS

We utilized a prospective randomized controlled study design performed at a suburban ED with an annual patient census of 80,000. All patients from 18 to 55 years of age with a chief complaint of back pain were eligible if the treating emergency physician diagnosed musculoskeletal LBP from a bending or twisting injury within the last 48 h of moderate or greater intensity (≥5 on a 10-cm visual analog scale [VAS]). Patients with acute exacerbation of chronic back pain were not excluded. Exclusion criteria were blunt trauma to the lower back, neurological motor deficits of the lower extremities, neoplastic disease, fever, pregnancy, current use of steroids or other immunosuppressive therapy, diabetes, uncontrolled hypertension, significant peptic ulcer disease, cataracts, urinary tract infection, allergy to prednisone, lactose intolerance, visits from a local occupational medicine program, and refusal to participate.

Physicians completed a standardized data collection instrument that included demographic, historical, and clinical questions. The treating emergency physician decided on the analgesic therapy in the ED, but this could not include corticosteroids. After enrollment, patients were randomized to the study or placebo group by computer randomization in a double-blind fashion. Allocation to each group was concealed. Those receiving the study medication were given 50 mg of prednisone by mouth and four doses of the same medication to take home (50 mg daily). The placebo group received the same regimen as the study group, using an inactive tablet that was prepared in the hospital pharmacy and was identical in appearance to the prednisone. All study participants, clinicians, and study personnel were blinded to group assignment until all data collection was completed. Patients were discharged home with additional rescue medications, prescribed at the discretion of the treating attending emergency physician. Pain assessment was recorded at the time of ED arrival and discharge using a 10-cm visual analog scale. In addition, all patients received telephone follow-up at 5–7 days. This was performed by a blinded study investigator who utilized a standardized data collection instrument to assess the primary outcome of pain based on a 0–3 verbal rating scale (VRS: none = 0, mild = 1, moderate = 2, severe = 3) as well as functional status. In addition, all patients were assessed for possible side effects, medication compliance, and patient satisfaction (1–5 point scale, 1 = very unsatisfied, 5 = very satisfied).

We a priori arbitrarily chose a difference of 0.6 as a clinically important difference on the 0–3 pain scale. A preenrollment power calculation determined that 29 patients were needed in each group to have a power of 80% to detect a 0.6 average difference between the two groups, with $\alpha = 0.05$ and SD of 0.8. Enrollment began in November 2005 and was completed in May 2009.

Data were entered into Microsoft Excel for Windows (Microsoft Corporation, Redmond, WA) and transferred into SPSS for Windows (IBM, Armonk, NY) for statistical analysis. Categorical variables were analyzed by chi-squared, interval data by Mann-Whitney, and continuous variables by Student's *t*-test. All tests were two-tailed with alpha set at 0.05. The main study outcome was the subject's pain at 5 days on the 0–3 scale. Secondary outcomes included a dichotomized pain scale (none or mild), whether the patient received further medical evaluation, whether the patient resumed normal household chores, whether the patient needed further evaluation from their personal doctor, whether the patient was able to return to work, and days out of work. Data analysis followed the intention-to-treat principle. The study was approved by the institutional review board.

RESULTS

Seventy-nine subjects were enrolled. Of these, 12 (15%) were lost to follow-up, leaving 32 and 35 patients, respectively, in the prednisone and placebo arms (Figure 1). The mean age was 40 (SD 9) years, and 30% (SD 6%) were female. The two study arms had similar demographics, initial and discharge ED pain scales, and pain prescriptions given at discharge, as seen in Table 1. The characteristics of subjects lost to follow-up differed little from those of the entire group (Table 1).

The main study end point, pain at 5 days on the 0–3-point scale, was similar between the two groups (absolute

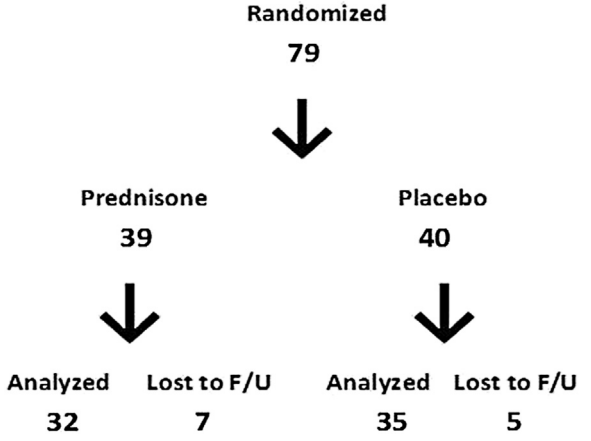

Figure 1. Enrolled participants. F/U = follow-up.