Annals of Internal Medicine | ORIGINAL RESEARCH

Methylprednisolone Injections for the Carpal Tunnel Syndrome

A Randomized, Placebo-Controlled Trial

Isam Atroshi, MD, PhD; Magnus Flondell, MD; Manfred Hofer, BSc; and Jonas Ranstam, PhD

Background: Steroid injections are used in idiopathic carpal tunnel syndrome (CTS), but evidence of efficacy beyond 1 month is lacking.

Objective: To assess the efficacy of local methylprednisolone injections in CTS.

Design: Randomized, placebo-controlled trial. (ClinicalTrials.gov: NCT00806871)

Setting: Regional referral orthopedic department in Sweden.

Patients: Patients aged 18 to 70 years with CTS but no previous steroid injections.

Intervention: Three groups (37 patients each) received 80 mg of methylprednisolone, 40 mg of methylprednisolone, or placebo. The patients and treating surgeons were blinded.

Measurements: Primary end points were the change in CTS symptom severity scores at 10 weeks (range, 1 to 5) and rate of surgery at 1 year. Three patients had missing 10-week data. All patients had 1-year data.

Results: Improvement in CTS symptom severity scores at 10 weeks was greater in patients who received 80 mg of methylprednisolone and 40 mg of methylprednisolone than in those who received placebo (difference in change from baseline, −0.64 [95% CI, −1.06 to −0.21; $P = 0.003$] and −0.88 [CI, −1.30 to −0.46; $P < 0.001$], respectively), but there were no significant differences at 1 year. The 1-year rates of surgery were 73%, 81%, and 92% in the 80-mg methylprednisolone, 40-mg methylprednisolone, and placebo groups, respectively. Compared with patients who received placebo, those who received 80 mg of methylprednisolone were less likely to have surgery (odds ratio, 0.24 [CI, 0.06 to 0.95]; $P = 0.042$). With time to surgery incorporated, both the 80- and 40-mg methylprednisolone groups had lower likelihood of surgery (hazard ratio, 0.46 [CI, 0.27 to 0.77; $P = 0.003$] and 0.57 [CI, 0.35 to 0.94; $P = 0.026$], respectively).

Limitation: The study was conducted at 1 center, and wrist splinting had previously failed for all patients.

Conclusion: Methylprednisolone injections for CTS have significant benefits in relieving symptoms at 10 weeks and reducing the rate of surgery 1 year after treatment, but 3 out of 4 patients had surgery within 1 year.

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For author affiliations, see end of text.

The carpal tunnel syndrome (CTS) is a common reason for persons to seek health care (1). Patients are initially treated with wrist splinting, but many have surgery. In the United States, carpal tunnel release surgery is done yearly in approximately 25 women and 13 men per 10 000 adults (2). Although surgery produces good outcomes (3), it has disadvantages, which are mainly surgery-related pain, hand weakness, and complications from surgery (4). The costs of postoperative work absence, which usually lasts several weeks, are high (3, 5). Thus, nonsurgical treatment, if effective, would have many advantages. In a recent survey of U.S. hand surgeons, 80% of the respondents reported use of steroid injections in CTS (6). A systematic review of studies published through May 2006 (7) found only 2 good-quality, double-blind, placebo-controlled trials involving 81 patients (8) and 60 patients (9). The review concluded that local corticosteroid injections provide clinical improvement 1 month after injection compared with placebo, but no randomized studies remained blinded beyond 1 month. No subsequently published placebo-controlled trials provide evidence of longer-term benefit. Also, no placebo-controlled trials have investigated possible dose–response relationships. We conducted a randomized, placebo-controlled trial to assess the efficacy up to 1 year of first-time local injection of 2 different doses of methylprednisolone in patients with idiopathic CTS.

METHODS

Design Overview

The study was a prospective, randomized, placebo-controlled, parallel-group trial that compared local injections of 80 mg of methylprednisolone, 40 mg of methylprednisolone, and placebo (1:1:1 ratio) in patients with idiopathic CTS who were not previously treated with steroid injections. The patients and orthopedic surgeons who administered the interventions were blinded. The trial has been previously described (10). Enrollment started in November 2008, and follow-up was completed in March 2012. The trial was approved by the Swedish Medical Products Agency, Uppsala, Sweden, and the Ethics Committee at Lund University, Lund, Sweden.

Setting and Participants

Patients referred by primary care physicians to 1 orthopedic department for evaluation were examined by trial investigators (orthopedic surgeons) and screened for eligibility. The inclusion criteria were primary idiopathic CTS,

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