A Randomized Study Comparing Corticosteroid Injection to Corticosteroid Iontophoresis for Lateral Epicondylitis

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Purpose We designed a prospective, randomized study to evaluate the effects of iontophoresis delivery of dexamethasone versus corticosteroid injection therapy on patient outcomes.

Methods We randomized 82 patients to 10 mg dexamethasone via iontophoresis using a self-contained patch with a 24-hour battery; 10 mg dexamethasone injection; or 10 mg triamcinolone injection. All patients received the same hand therapy protocol. Primary outcomes tracked were change in grip strength (flexion vs extension), pain, and function scores on a validated questionnaire. The secondary outcome was return-to-work status. Patients were evaluated at baseline, completion of physical therapy, and 6-month follow-up.

Results The iontophoresis patients had statistically significant improvement in grip strength at the conclusion of hand therapy compared with baseline. They were also more likely to get back to work without restriction. By 6-month follow-up, all groups had equivalent results for all measured outcomes.

Conclusions Dexamethasone via iontophoresis produced short-term benefits because for this group grip strength and unrestricted return to work were significantly better. This study suggests that this iontophoresis technique for delivery of corticosteroid may be considered a treatment option for patients with lateral epicondylitis. *(J Hand Surg 2012;37A:104–109.*

Type of study/level of evidence Therapeutic II.

Key words Corticosteroids, iontophoresis, lateral epicondylitis, randomized study.

Lateral epicondylitis is the most common overuse syndrome afflicting the elbow, with an incidence estimated at 4% annually.[1–3] This painful degenerative condition affects daily activities and work life. Although the condition is self-limiting in many, patients referred to surgeons often have had a prolonged disease course or multiple relapses. The spectrum of recommended treatment options includes patient education, behavioral modification, hand therapy, corticosteroid injection, and surgery.[4–7] Whereas literature can be found to support any number of interventions, there is a lack of prospective, randomized trials to guide treatment choices for lateral epicondylitis.[1,2] Despite the condition's prevalence and effect on work and lifestyle, little consensus exists on management. Surgery is usually reserved for recalcitrant cases. For most patients, the treatment aim is to break the cycle of pain using rest or medication and then slowly resume protected motion. Injection of corticosteroids is a standard intervention for pain relief for many enthesopathies including lateral epicondylitis.[4,7,8] Advocates can be found for all available corticosteroids. Recent studies suggest that lateral epicondylitis might not be an inflammatory process but a degenerative process, which would make the role of steroids more for pain relief

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The manufacturer of Iontopatch (Travanti Pharma Inc., Mendota Heights, MN) provided 20 iontophoresis patches after the authors exhausted the supply from their local durable medical equipment vendor.

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than for an anti-inflammatory effect.[4] Although the use of steroids has short-term benefits, there are inherent risks to the use of an anti-vulnerary agent directly into the site of degenerative changes.[2,4] Steroid use can block the release of prohealing cytokines, thereby negatively impacting tissue's reparative ability.

Iontophoresis offers an opportunity to deliver medication without injection or deep penetration of the medication. It is a transdermal drug delivery method that uses a small electric current applied to the skin to drive the ionically charged steroid medication through the skin.[4,9] Evidence suggests that dexamethasone administration via iontophoresis is an effective, noninvasive means of decreasing acute pain in lateral epicondylitis.[1,10] Advantages of iontophoresis include its noninvasive nature, uniform absorption, and absence of systemic side effects such as gastrointestinal distress.[3,5] This study used an iontophoresis electrode and reservoir with an integrated battery that allows the treatment to be performed over 24 hours rather than the traditional 20 to 60 minutes. This device can potentially deliver higher levels of medication over 24 hours than in a traditional therapy session.

Because this innovation had not been studied for its utility in this patient population, we aimed to define the role of dexamethasone delivered via a self-contained iontophoresis device for patients with lateral epicondylitis. We hypothesized that dexamethasone via the iontophoresis battery patch would improve patient outcomes compared with local injection of corticosteroid medication.

MATERIALS AND METHODS

We performed a prospective randomized study in the outpatient setting between May 2006 and April 2009 at our urban institution. Three plastic surgeons participated in the study. The study was approved by the hospital's institutional review board and was listed on the National Institutes of Health clinical trial Web site (clinicaltrials.gov, number NCT00257634). We obtained informed consent from each subject.

Patients eligible for inclusion in the study ranged in age from 18 to 70 years, with a diagnosis of lateral epicondylitis made by local tenderness to palpation just distal and anterior to the lateral epicondyle. Provocative testing included pain with elbow extension, forearm pronation, and wrist flexion (Mille test), or pain with resisted extension of the middle finger (Maudsley test). Patients were excluded if they were pregnant, had a history of fibromyalgia or elbow surgery, had a duration of symptoms greater than 2 years, used steroid medication within the previous 6 months, or had bilateral involvement. We also excluded patients with bony abnormalities around the elbow or restricted elbow function.

The study design involved 3 treatment groups. Group 1 patients received the electronic transdermal drug delivery device (Iontopatch; Travanti Pharma Inc., Mendota Heights, MN) placed by the hand therapist. Using 10 mg dexamethasone placed in the reservoir, the iontophoresis patch remained in place for 2 days. A second patch was applied 2 to 10 days after removal of the first patch if the patient could not advance from the stretching phase to the strengthening phase of the therapy program because of pain. Group 2 patients received a 10-mg intramuscular/intratendinous dexamethasone injection (Bristol Meyers Squibb Pharmaceuticals, New York, NY) into the area of maximal pain. Group 3 patients received a 10-mg injection of intramuscular/intratendinous triamcinolone (Bristol Meyers Squibb Pharmaceuticals) into the area of maximal pain.

Patients were randomized during enrollment. We started hand therapy after randomization and standardized it for all 3 groups based on the published therapy protocol in Hunter and Callahan.[11] We divided the 8-week therapy protocol into 3 sections consisting of rest, mobility, and strengthening. Beginning in the rest phase, we treated randomized patients with 1 of the 3 medications described. During the mobility phase, patients were taught stretching exercises to increase range of motion. In the strengthening phase, patients were taught standardized exercises to increase strength and overall function. The strengthening phase began only after subjects were free of medication for 24 hours.

Primary outcome measures included grip strength change, and pain and function as measured by results of the patient-rated tennis elbow evaluation (PRTEE) questionnaire. The PRTEE is a validated patient outcome instrument specifically designed for lateral epicondylitis.[12,13] This was chosen for relevance to the disease process, high internal consistency, and highest responsiveness to change compared with many other validated questionnaires.[13] We tracked outcome measures at the beginning of the study (baseline), completion of treatment, and 6 months after treatment.

Patients ranked pain for a number of activities using a scale from 0 to 10, with 10 being the worst pain. Ten questions evaluated function in the affected limb. Higher scores on the function scale correspond to more difficulty completing activities of daily living.

Grip strength difference in elbow flexion and extension was performed in the manner outlined by Dorf et al.[14] We used change in grip strength because decreased strength with elbow extension can be diagnostic of