

**Scarpone M, Rabago DP et al. The Efficacy of Prolotherapy for Lateral Epicondylitis: A Pilot Study. Clin J Sport Med 2008;18:248-254.**

Design: Randomized clinical trial

Population/sample size/setting:

- 20 patients (10 men, 10 women, mean age 48) with lateral epicondylitis (LE) treated in a university department of family medicine in Wisconsin
- Eligibility criteria were a diagnosis of LE and elbow pain for at least 6 months with failure of each of these conservative approaches: rest, physical therapy, NSAID, and 2 corticosteroid injections
- Exclusion criteria were diabetes, steroid injection in past 6 weeks, and self-reported immunocompromised status

Main outcome measures:

- Randomized to prolotherapy (PrT) injection (n=10) or normal saline injection (n=10)
- PrT group received 1.5 ml of a solution containing 50% dextrose, 5% sodium morrhuate, 4% lidocaine, and 0.5% bupivacaine
- Control group received 1.5 ml of normal saline only
- Injections were given with opaque syringe at 3 injection sites: the supracondylar ridge, the lateral epicondyle, and the annular ligament
- Injections were done at baseline and at 4 and 8 weeks
- Outcomes were measured at baseline and at 8 and 16 weeks
- Main outcome was pain VAS on a 10 point scale; secondary outcomes were isometric resistance strength resting grip strength
- At 52 weeks, telephone interviews were done and subjects were asked 3 follow-up questions: elbow pain, whether elbow pain interfered with activities of daily living (ADL), and whether they had used other therapies since completion of injections
- VAS pain scores improved in PrT group from a mean baseline score of 5.1; at 16 weeks, 6 patients had VAS of 1 and 4 patients had VAS of 0
- VAS scores did not improve in the control group from the mean baseline score of 4.5; at 16 weeks, their mean VAS was 3.5, and no patient had a score of 0 or 1
- Isometric strength improved in PrT group from 13.3 at baseline to 30.5 at 16 weeks; the control group had no similar improvement (10.3 at baseline and 11.3 at 16 weeks)
- Grip strength data were less definitive; both groups were variable and improved from baseline
- At the 52 week telephone interview, 6 PrT patients reported no elbow pain limiting ADL, 2 had mild pain with no impact on ADL, and 2 reported modest impact on ADL; none of the PrT group had sought additional therapy
- At 52 weeks, 1 control patient had no pain, 8 reported pain sufficient to interfere with ADL, and 1 was lost to follow-up; 4 control patients had sought

additional therapies (2 had surgery, 1 had extracorporeal shock wave, and 1 had acupuncture)

- Adverse effects were minimal; two PrT patients had post-injection erythema and pain which resolved using acetaminophen and codeine

Authors' conclusions:

- Prolotherapy was well tolerated and was more effective than saline in reducing pain and increasing isometric strength
- Prolotherapy is a reasonable therapeutic option for lateral epicondylitis

Comments:

- Authors point out some limitations of their study: a validated disease-specific questionnaire was not used and grip strength assessment may have been compromised by use of a non-standard technique
- Study is well-planned and thoughtfully executed, taking measures to ensure blinding of injections and concealment of allocation
- Pain is the main outcome, and while strength is useful information, a functional score would have improved the study's relevance for a guideline
- Even with small sample, there are notable differences between the groups; none of the PrT patients sought additional treatment in the year after injections were completed; and they reported fewer limitations on ADL
- Although no adverse effects are reported, the sample is too small to detect events that could occur not infrequently in clinical practice

Assessment: Adequate as a pilot study, but inadequate for an evidence statement in a guideline (too few observations to detect adverse effects, lack of functional information)