

Haake M, Konig IR et al. Extracorporeal Shock Wave Therapy in the Treatment of Lateral Epicondylitis. JBJS 2002;84-A:1982-1991.

Design: Randomized clinical trial

Population/sample size/setting:

- 271 patients (128 men, 143 women, mean age 46) referred for treatment of lateral epicondylitis [LE] to community and university orthopedic departments in Germany and Austria
- Eligibility criteria included at least 6 months of conservative treatment, with at least 3 local injections, 10 sessions of PT, at least 2 weeks elapsed since last treatment, and Roles/Maudsley score of 3 or 4 (discomfort with activity or pain limiting activity)
- Exclusion criteria included local arthritis, rheumatoid arthritis, bilateral symptoms, nerve entrapment or other neurological findings, coagulation abnormalities, pregnancy, and infection of the extremity being treated

Main outcome measures:

- Randomized to active ESWT (n=134) or placebo (n=137)
- Active ESWT was delivered in 3 sessions approximately 1 week apart, using low energy (0.07 to 0.09 mJ/mm²), with 2000 pulses per session, following local anesthesia with mepivacaine
- Sham ESWT was administered with the same local anesthesia and the same device with an air-filled polyethylene foil reflecting the shock wave energy
- Primary outcome was "success" defined as a Roles/Maudsley score of 1 or 2 (no pain/full activity or occasional pain/full activity) at the end of 12 weeks, provided that the patient had received no additional conservative or surgical treatment during that time interval
- At 12 weeks, success was recorded in 32 of 124 active ESWT and in 31 of 122 sham ESWT patients
- The secondary end points (success at 12 months and pain-free grip strength) were also nearly equal in the two treatment groups
- Side effects were observed more commonly in the active ESWT than in the sham group; 31% of the ESWT group and only 8% of the sham group had reddening; 11% of the ESWT group and 4% of the sham group had pain

Authors' conclusions:

- ESWT has no therapeutic effect greater than placebo, and ought not be offered as a treatment for LE except in the setting of a randomized trial
- The conditions of the trial (local anesthesia, energy density) reflect the way that ESWT has been commonly applied in clinical practice
- Measurements of flux density (mJ/mm²) are subject to large errors due to technical problems with measurement, and the exact flux density is not meaningful

Comments:

- With the number of patients followed up at 12 weeks, a power calculation (arcsine method) estimates that the sample had nearly 90 % power to detect the clinically important effect size (55% vs. 33% success rate) specified by the authors
- The contrast with the “positive” result reported by Rompe et al in 2004 may be due to a different patient population
- Rompe studied tennis players in a single facility with a single ESWT operator
- Haake et al studied a less restricted patient population in a multi-center setting, and may be more applicable to the settings in which a guideline would be operative

Assessment: High quality.